Clinical communication

Defining, assessing, and improving the sharing of complex treatment information with multiple sclerosis patients

by

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Abbreviations

AHSCT - autologous haemopoietic stem cell transplantation

AV -atrioventricular

CNS – central nervous system

Count-COPIN - Counting Complex Orally Provided INformation

Count-PROPIN - Counting Patient Recall of Orally Provided INformation

DMF - dimethyl fumarate

DMT - disease modifying therapy

IRL – in real life

JCV – John Cunningham virus

JG – Jennifer Gerwing, researcher

JN - Jenny Nordfalk, Ph.D.- candidate

LARP - live action roleplay

LTM - long-term memory

MG – Magne Nylenna, researcher

MRI – Magnetic resonance imaging

MS – Multiple Sclerosis

NEDA – no evidence of disease activity

NON-PORT – non-portioning

PORT – portioning

PG – Pål Gulbrandsen, researcher

RCT – Randomized controlled trial

RR-MS – Relapsing Remitting Multiple Sclerosis

SD – Standard deviation

SDM – shared decision-making

STM - short-term memory

UoI - Unit of Information

WM – working memory

Figure and table list

1. List of Publications

I. Nordfalk J.M., Gulbrandsen P., Gerwing J., Nylenna M., Menichetti J. Development of a measurement system for complex oral information transfer in medical consultations. BMC Med Res Methodol. 2019;19(1):139. Published 2019 Jul 4.

II. Nordfalk J.M., Menichetti J., Thomas O., Gulbrandsen P., Gerwing J. Three strategies when physicians provide complex information in interactions with patients: How to recognize and measure them. Patient Educ Couns. 2021 Oct 13.

III. Nordfalk J.M., Holmøy T., Thomas O., Nylenna M., Gulbrandsen P. Training physicians in providing complex information to patients with multiple sclerosis: a randomised controlled trial. BMJ Open 2022;12:e049817. doi:10.1136/bmjopen-2021-049817

2. Summary

English summary

Modern health care and legislation place high demands on physicians to inform their patients, yet little training is offered them. Information sharing between physicians and patients has a lot of improvement potential[1]. Medical information-giving generally does not reflect the existing knowledge on the field on how to organize and present information in the best possible way. The evidence for the effectiveness of different medical information-giving strategies is inconsistent, and there is a need for better methods when testing them[2].

Multiple sclerosis (MS) is a chronic autoimmune disease resulting in demyelination and neurodegeneration in the central nervous system (CNS). Its clinical course is characterized by a relapsing-remitting phase with local inflammation leading to fully or partly transient neurological deficits followed by a secondary progressive phase with a steady neurodegenerative deterioration[3]. For the individual, relapsing-remitting multiple sclerosis (RR-MS) is a fundamentally unpredictable disease, as one cannot predict if or when a relapse may occur. When we embarked on this study, patients used to receive first-line treatments at an early stage of their disease, while more effective second-line or escalation treatments were introduced once these had failed. In the case of deciding whether to start second line treatment in multiple sclerosis, and which treatment to choose, the patient needs enough knowledge about prognosis, the pros and cons of the treatment options, and the insecurity concerning all of these.

The thesis' overall aims are to improve complex unscripted treatment information sharing from physicians to patients with chronic disease facing difficult treatment choices. To accomplish that and understand mechanisms, we needed to define information units provided and recalled, measure them, and define and measure specific physician behaviours during information sharing.

We chose information about MS escalation treatment as our model in this study, because of the huge challenge it is for the physician to convey sufficient information to the patient in a both very complex informative setting and a possibly emotional situation.

The first paper describes the development of a reliable counting system of provided and recalled complex information about drugs in unscripted conversation. We wanted to see if it was possible to measure the efficacy of a communication training intervention on the outcome recall in a randomized controlled trial (RCT), (see paper III below), analog to a drug effect study, which is rare in health intervention studies. This meant that we needed methods to quantify both the amount of information given, and the amount of information a patient remembers.

The second paper describes how we developed methods on how to evaluate whether the physicians utilized certain strategies meant to enhance information-giving more often after the communication training intervention in the RCT in paper III. This included operationalizing the strategies in a way that enabled us to measure them. Such translational research could further the insight in the microprocesses of communication and in how to operationalize them and measure them.

The third paper is an RCT, measuring the effect of a communication training intervention specifically aimed at neurologists giving uncertain, complex and unscripted information about MS escalation treatment options, on patient recall rate. We also wanted to see if they provided fewer information units after having been taught this strategy in the intervention, and whether the intervention had an effect on patient involvement, measured by questionnaires.

We used thirty-four patients recently diagnosed with RR-MS and currently on none or first-line treatment. We asked them to pretend that they had had recent relapses and were now to consult with a neurologist about escalating their treatment and discuss different treatment options. The patients were randomized so that half of them each consulted with one of seventeen neurologists before the latter had received training, while the other half consulted with the same neurologists after they had received training.

We found that our training intervention did indeed succeed in changing the physicians' behaviour so that they provided less units of information after the training. They did not change their behaviour in the other three strategies taught in the intervention, which included (1) *mapping the patient's preferences* and (2) *checking the patient's understanding,* and (3) *portioning information*. The intervention towards the physicians did not result in increased patient recall rate.

Norwegian summary / sammendrag på norsk

Dagens helsevesen og lovgivning stiller høye krav til leger når det gjelder pasientinformasjon. Likevel tilbys de lite trening i dette. Det finnes rikelig potensiale for forbedring i den eksisterende informasjonsutvekslingen fra lege til pasient[1].

Medisinsk informasjons-giving reflekterer generelt ikke den eksisterende kunnskapen på feltet om hvordan informasjon bør organiseres og presenteres best mulig. Det er manglende evidens for hvor effektive de ulike kommunikasjonsstrategiene faktisk er, og det er behov for bedre evaluerings metoder [2].

Multippel sklerose (MS) er en kronisk, auto-immun sykdom som resulterer i demyelinisering og nerve-degenerasjon i sentralnervesystemet. Den kliniske utviklingen karakteriseres av en initial relapserende-remitterende fase med attakk-vis lokal inflammasjon som leder til helt eller delvis forbigående nevrologiske utfall, fulgt av en sekundær progressiv fase med jevn, gradvis nevrodegenerativ forverring[3]. For individet er relapserende-remitterende multippel sklerose (RR-MS) en sykdom preget av grunnleggende uforutsigbarhet, siden man ikke kan forutsi hvis eller når et attakk vil forekomme. Da denne studien var i startgropen, var det vanlig at pasientene fikk behandling med førstelinje-medikamenter i sykdommens tidlige stadier, og at man introduserte annenlinje-medikamenter dersom disse ikke viste seg å fungere godt nok.

For å kunne være med og velge hvorvidt man skal begynne med annenlinjebehandling mot MS, og hvilket medikament man i så fall skal velge, trenger pasienten nok kunnskap om prognose, fordeler og ulemper ved de ulike alternativene, og kunnskap om usikkerheten som hefter ved alle disse.

Denne avhandlingens overordnede mål er å forbedre kompleks, ikke forhåndsdefinert, behandlingsinformasjon gitt av leger til pasienter med kronisk sykdom som stilles overfor vanskelige behandlingsvalg. For å oppnå dette og forstå mekanismene, måtte vi definere informasjonsenhetene som ble formidlet og gjengitt, måle dem, og i tillegg definere og måle spesifikk legeadferd under informasjonsdelingen. Vi valgte å bruke informasjon om eskalering av MS-behandling som modell i denne studien fordi nettopp denne situasjonen medfører at det å formidle tilstrekkelig informasjon til pasienten er en enorm utfordring for legen. Dette fordi settingen både innebærer svært kompleks informasjon, i en situasjon som også kan være emosjonell for pasienten.

Den første artikkelen beskriver utviklingen av en pålitelig metode for å telle både gitt og gjenkalt kompleks informasjon om medikamenter i fritt improvisert samtale. Vi ville se om det var mulig å måle effekten av en atferdsmessig intervensjon på utfallet gjenkalling med en randomisert kontrollert studie, noe som er uvanlig innenfor helseintervensjonsforskning. Det vil si at vi trengte

metoder for å kvantifisere både mengden informasjon som ble gitt og mengden informasjon pasienten gjenkalte etterpå.

Den andre artikkelen beskriver hvordan vi utviklet metoder for å evaluere hvorvidt legene benyttet visse kommunikasjonsstrategier ment å skulle forbedre informasjonsgivning, hyppigere etter at de hadde gjennomgått kommunikasjonskurset i det randomiserte kontrollerte studien i artikkel III. Strategiene ble også operasjonalisert på en måte som gjorde det mulig for oss å måle dem. Slik translasjonsforskning vil kunne føre til ny innsikt i mikroprosessene som finner sted ved kommunikasjon, og i hvordan man kan operasjonalisere dem og måle dem.

Den tredje artikkelen er en randomisert kontrollert studie. Den måler effekten av en intervensjon i form av et kommunikasjonskurs spesifikt rettet mot nevrologer som uten manus skal gi usikker og kompleks informasjon til MS-pasienter om de ulike alternativene for andrelinje-medikamenter. Effekten måles i gjenkallingsprosenten til pasientene. Vi ville også se om nevrologene reduserte antallet informasjonsenheter etter å ha blitt undervist i denne strategien på kurset, og om kurset hadde effekt på pasientmedvirkning, målt ved hjelp av spørreskjemaer.

Trettifire pasienter som nylig var blitt diagnostisert med RR-MS, og som enten brukte førstelinje-medikamenter eller ikke tok noen medisiner i det hele tatt, deltok i studien. Vi ba dem om å forestille seg at de hadde hatt attakker nylig, og at de skulle komme til en nevrolog for å få informasjon om og diskutere de ulike alternativene for annenlinjebehandling. Pasientene ble randomisert slik at kontrollgruppen møtte en av sytten nevrologer før disse hadde vært på kurset, mens intervensjonsgruppen møtte de andre nevrologene etter at de hadde vært på kurset.

Vi så at kurset lyktes i å endre legenes adferd på den måten at de ga færre informasjonsenheter etter at de hadde vært på kurs. De endret ikke adferden sin i signifikant grad når det gjaldt de andre tre strategiene de fikk opplæring i; (1) å kartlegge pasientens preferanser, (2) å kontrollere at pasienten har forstått, og (3) å porsjonere ut informasjon. Kursingen av legene resulterte ikke i økt informasjonsgjenkallingsratio for pasientene.

3. Introduction

3.1. Multiple sclerosis

Multiple sclerosis (MS) is one of the most common chronic conditions affecting the central nervous system (CNS). It is also the most common cause of non-traumatic disability in young adults in the Western world[4]. MS was first described by Jean-Martin Charcot, neurologist at the Hôpital de Salpétrière in 1868, as 'la sclérose en plaques', the name literally meaning “many scars”[5]. MS is an autoimmune disease triggered by environmental agents acting in genetically susceptible people. The disease is more common in women, affecting thrice as many women as men in Norway[6]. A recent study shows a 32-fold risk increase of MS after infection with the Epstein-Barr virus, results that suggests Epstein-Barr virus as the leading environmental cause of MS[7].

MS is a disease in which the immune system attacks the CNS through lymphocytes causing local inflammation[3]. Both the insulating myelin nerve sheaths and the nerve axons are damaged. The loss of myelin disrupts transmission of electrical impulses to and from the brain. This leads to neurological symptoms like blurred vision, pain, numbness, intentional tremor and loss of movement and function. About 85% of the subjects experience an initial attack from which they make a full or partial recovery (relapsing-remitting MS). Immune-mediated axon damage cause permanent neurological deficits. Axonal transection and demyelination cause neurodegeneration and brain atrophy[8]. It is a disease with an unpredictable course, as it is not possible to predict if or when another attack will follow[9].

There are three main management strategies[10]:

1. Countering the autoimmune inflammation in an acute attack.
2. Symptomatic therapies.
3. Reducing biologic activity through disease-modifying therapies.

Disease-modifying therapies are aimed at preventing another attack, with “No Evidence of Disease Activity” (NEDA) as the ultimate goal[11]. There is a continuous development in this field, with highly effective therapies approaching NEDA. The current therapies does not yet give enough protection against the neurodegenerative properties of the disease[10]. An alternative treatment option in patients with severe, treatment-resistant relapsing-remitting MS (RRMS) is autologous haematopoietic stem cell transplantation (AHSCT)[12].

Most patients will eventually develop secondary progressive disease, which encompasses a steady deterioration over time, without remission, leading to increasing impact on health-related quality of

life[13]. When this stage is reached, treatment is only symptomatic. Current immune modulatory treatment in MS aspires to slow the advance of progressive functional impairment in RRMS[10].

At the time when this study was designed and conducted, the national guidelines for MS treatment established by the Norwegian Directorate of Health followed the principle of escalation, meaning first-line and second-line treatment. Initial treatment should in most cases be what was called first-line treatment (interferon beta 1a/b and glatiramer acetate). These drugs had limited effect, but also a relative lack of serious adverse events[14]. Another option within first-line treatment at the time was Dimethyl fumarate (DMF). DMF has a long history as a both topical and orally administered treatment for psoriasis[15]. As its immunomodulatory properties were discovered, rigorous testing was conducted and Class 1 evidence supports its use in MS[16-18]. With the option of an oral mode of administration combined with a well-defined safety profile, DMF found its place as an oral first-line therapy option for the treatment of relapsing forms of MS[19].

In a situation of disease progression during first-line treatment, the national guidelines recommended a treatment escalation to second-line drugs[14]. These drugs are more effective, but they also have more serious, sometimes dangerous side-effects. The relevant escalation drugs at the time of this study were natalizumab, fingolimod and alemtuzumab. With growing experience of the first two, they have been more commonly used as the first agent in patients with highly active disease at onset as well[20].

- Natalizumab is a recombinant humanized monoclonal antibody that inhibits binding of the α4 subunit of the α4β1 and α4β7 integrins to their endothelial receptors and prevents trafficking of mononuclear leukocytes across the vascular endothelium of the central nervous system (CNS). It is administered by monthly infusion. It has been proved highly effective, with approximately 70% reduction in the risk of clinical relapses and approximately 50% reduction in the risk of disability progression compared to placebo[21].
- Fingolimod is a sphingosine-1-phosphate–receptor modulator that prevents the egress of lymphocytes from lymph nodes. It is taken orally once a day. Fingolimod reduces the risk of relapse and disability progression compared to placebo with approximately 55% and 30% respectively[22].
- Alemtuzumab is a humanized monoclonal antibody that depletes CD52-expressing lymphocytes. It is administered with daily infusions for five days, followed by daily infusions for three days one year later. Some patients may need retreatment beyond the two initial cycles. The drug has not been tested against placebo, which makes it more complicated to

compare its efficacy with that of natalizumab or fingolimod. Tested against interferon beta-1a, it has been shown to reduce the yearly relapse rate with up to 55%, and to reduce progression of disability over two years with 30-42%[23].

All three drugs have uncommon, but severe, adverse effects. For natalizumab the gravest concern is a risk of reactivation of John Cunningham virus (JCV) leading to progressive multifocal encephalopathy (PML), a potentially lethal opportunistic brain infection. Treatment with natalizumab reduces the natural immunosurveillance of the central nervous system, which increases the risk of opportunistic infections[24]. All treated with natalizumab must therefore be checked for JCV antibodies. patients with MS who have not been previously exposed to the infection have an almost non-existent risk of PML (<0.09/1000) when treated with natalizumab. But for those who are JCV antibody-positive, the risk of PML is increasing depending on the length of natalizumab treatment, the amount of antibodies detected and previous use of immunosuppressants[25] and an algorithm for stratifying the risk of PML during natalizumab treatment has therefore been developed[24]. Alemtuzumab involves a high risk of developing other autoimmune conditions and a risk for treatment-related vascular complications, while fingolimod reduces heart rate and slows AV conduction, and carries a risk for uveitis and macular edema. Both increase the risk for infections[26]. The three all have other side-effects, but these are the most severe.

At the time when this study was planned and run it was medically defendable to choose any of these three options for a patient in need of escalation therapy. To decide which drug is the best fit for the individual patient incorporates not only considerations of efficacy but also toxicity, safety and compatibility with pregnancy. This is a complex situation where the need for good communication and a tailored approach is imperative[27], both to achieve treatment adherence[28, 29], patient satisfaction[30] and to fulfill the demands of Norwegian legislation[31]. Patients tend to underestimate risks and overestimate benefits of disease-modifying therapies (DMT's)[32]. We believed that we had expertise to hold a training program for the neurologists that would result in better information giving.

Since we began this study, the development of disease-modifying therapies in MS has rapidly evolved. The treatment options, and the balance between them, are now quite different, and the concepts of first-line and second-line treatment have been challenged by the recommendation of early use of highly effective disease-modifying therapies, as the latter substantially improves the

prognosis[3, 10]. In 2020, 14 different DMT's were approved in the European Union (EU). Still, direct comparative data does not exist for each DMT with all the alternatives[33]. Treatment has become more individualized, and off-label treatment with rituximab, an anti-CD20 B-cell depleting agent, is increasingly becoming the preferred option for treatment naïve patients with highly active MS in Norway[34] as it has been in Sweden for years[35]. Rituximab has been shown to be safe and effective for patients with MS[36], and recent retrospective observational studies suggest that it is superior to many DMT's in reducing disease activity and maintaining long-term treatment[37, 38]. Autologous haemopoietic stem cell transplantation (AHSCT) is an alternative treatment approach. It is the most successful at achieving prolonged status of NEDA, but it is associated with high risk[39]. With increased expertise, the risks of AHSCT has however decreased to levels acceptable for patients with an aggressive MS disease[40].

3.2. Information sharing

3.2.1. Medical communication

Communication is one of the keystones of good medical care, and information sharing lies at the heart of medical communication. Information is given for several reasons: it improves insight in the patients' health problem and treatment options, it is the basis for decision making, it reduces uncertainty, and supports coping efforts as well as patient autonomy[41, 42]. Almost all patients claim to desire full information[43-46]. The patients want more information than the physicians think they do[47]. The information needs are individual[27, 47, 48]. Patients do not remember a great portion of the provided information[49-51], and comprehension has also been shown to be limited[52-55]. Those who prefer more information, remember a higher proportion of information than those who prefer less information[56], and pre-existing medical knowledge has been shown to have a positive association with recall[57].

One of our goals as physicians is to provide the individual patients with information tailored to their needs in the best possible way; so that the patient has the ultimate chance of understanding it, remembering it, and thus adhere to recommended treatment[1, 50]. It is important to note that high patient satisfaction does not correlate with high patient recall[58, 59].

Information sharing from physician to patient mostly happens in medical dialogue, with other techniques or instruments as supportive tools. This thesis is limited to the subject of oral provision of unscripted medical treatment information.

3.2.2. Historical development of the doctor-patient relationship

The doctor-patient relationship is depending on the medical, socio-political and intellectual-scientific climate at the time, as the examples from Western medical history below illustrates:

In ancient Egypt the doctor-patient relationship is believed to have evolved from that of priest-supplicant, and was most probably quite healer/doctor dominated[60].

Many modern medical ethicists view the relationship between physician and patient in the Classical Greek era as paternalistic; a non-spoken agreement that the physician had a professional duty to do what he considered best for the patient, and the patient had a duty to accept the treatment the physician saw fit to prescribe. Still, there are medical texts from the Hippocratic era that support a more egalitarian approach; instructing budding physicians to secure the cooperation of their patient, to listen to the patient's history, to speak plainly, to be forthright and disclose good and bad

prognoses both. The integrity of the professional was consolidated with the Hippocratic oath, and the relationship can be viewed as leaning toward partial egalitarianism[61].

During the Middle Ages, the doctor-patient relationship weakened and became influenced by magic-religious beliefs; illness were seen as punishment for sins, deviant ideas were quickly branded as witchcraft or blasphemy, and the doctor, often a religious scholar, became high-ranked and dominated the relationship[60].

In the sixteenth century, the Bohemian physician George Handsch had the foresight to record oral expressions physicians at the time used when explaining the reason and treatment for an ailment to patients and their families. He found that the terms and concepts used had to make sense to ordinary people. The model of illness was an interpretation of the symptoms. The physicians needed to respect their patients' beliefs and preferences if they were to gain trust, be hired and get paid[62]. This shows that at times, the relationship was patient dominated.

As medical treatment became more organized in hospitals in the 18th century, and a biomedical view of illness prevailed, patients became passive and compliant recipients of care, a care that sometimes consisted only of the verbally conveyed reassurance of an authoritative physician. Medical paternalism was thus considered necessary[60]. This did only increase with the development of scientific methods and the increased understanding of disease pathology and microbiology that came with the 19th century[63].

In the second half of the 20th century, we have had a shift from paternalism towards a greater degree of patient autonomy. Szasz and Hollender started to focus on the human relationship as an abstraction embodying two persons interacting. They set up three different models of the Physician-Patient relationship, all appropriate, but for different circumstances, as shown in their table below[64].

	Model	Physician's Role	Patient's Role	Clinical Application of Model	Prototype of Model
1.	Activity-passivity	Does something to patient	Recipient (unable to respond)	Anaesthesia, acute trauma, coma, delirium, etc.	Parent-Infant
2.	Guidance-cooperation	Tells patient what to do	Cooperator (obeys)	Acute infectious processes, etc.	Parent-Child (adolescent)
3.	Mutual participation	Helps patient to help himself	Participant in «partnership» (uses expert help)	Most chronic diseases, psychoanalysis, etc.	Adult-Adult

Kilde: Szasz TS, Hollender MH. A contribution to the philosophy of medicine; the basic models of the doctor-patient relationship. *AMA Arch Intern Med* 1956;97(5):585-92 page 586, Table 1.

Around the same time, the Hungarian psycho-analyst Michael Balint (1896–1970) attempted to combine medicine and psychoanalysis. He advocated a biopsychosocial model of illness, proposing that the relationship between physician and patient could be in itself therapeutic[65].

Ideas stemming from reactions to the paternalistic model evolved into alternative models of treatment decision making; Informed Consent, Informed Decision Making and Shared Decision Making (SDM). The practice of Informed Consent, the duty to not only obtain patients' consent before medical interventions, but adequately inform them, was established in 1957 in the California court of appeals case Salgo v. Leland Stanford etc.[66, 67]. With Informed Decision Making, Informed Consent was expanded to include more dialogue and less unidirectional disclosure of facts presented by the physician[68]. In SDM, introduced by Veatch in 1972[69], patient autonomy is held higher than traditionally in biomedical care. The physician is supposed to explain the condition and treatment alternatives to the patient and invite them to discuss treatment options in order to help them make decisions that fits their personal preferences and beliefs [70]. It was embraced by some as an ideal way of progressing from paternalism to partnership, while others found it problematic[71]. Many different conceptual definitions of SDM and related concepts co-existed in the following years, as reviewed by Makoul and Clayman, who also proposed an integrative model of SDM that built on the existing literature base at the time, including a set of elements that are essential for SDM to take place[72]. As most patients desire to actively participate in decision-making[45, 73], these elements could be seen as essential in all successful information provision about treatment options.

In 1976 the concept of Patient-Centredness was advocated by Byrne and Long[74], and in 1987 the Picker/Commonwealth Program for Patient-Centered Care was established to promote ways of providing patient-centered medical care[75].

The doctor-patient relationship has been through quite an evolution when it comes to patient autonomy and involvement in Western Civilization during the past half century. Doctors today are not only responsible for the medical expertise. The role has greatly expanded; not limited to, but absolutely including, giving information in an understandable manner, helping patients make decisions about treatment and support them in times of crisis. At the same time, the institutionalized health care has led to a loss of continuity and the 1:1 doctor-patient relation. The different schools on how patient integrity and autonomy should be best achieved are however ideals that may have been formulated before observed practice had been accurately described[76]. It is a difficult task to give complex medical information in such a manner that the patient is enabled to both understand and remember it well enough to participate in decision-making. It was this challenge that motivated the research group that initiated this study.

3.2.3. Information provision and patient participation in legislation

Between 1905 and 1914 the basic features of informed consent were formulated in American legislation introducing the concept that a patient has the right to make her own decisions about medical treatment and procedures performed on her body, which led to physician liability for lack of disclosure of risk information[77]. In 1957 the expression was coined in a court case [66].

In the ancient Hippocratic tradition, the physicians' responsibility was more moral than legal. This changed with the trial in Nuremberg in 1946, as a result of the inhumane and horrendous experiments performed by Nazi doctors. The Nuremberg Code[78] consolidated into a set of clinical research ethics rules the moral and ethical principle that science should never transform or consider human beings as an instrument to be employed for scientific purposes[79]. No nation has officially accepted the Code as law, but it has inspired other codes, rules and legislations worldwide[80], like the Declaration of Helsinki on medical research involving human subjects[81]. Enhancing patient participation in their own health care and treatment choices is today a central theme of both ethics and legislation in many countries. Usually, the law concerns itself with informed consent, while shared decision-making traditionally belongs to the field of ethics[82].

In Norway, The Patients' Rights Act of 1999 ensures the patient's right not only to information, but also to participation[83] in decisions about diagnostic work-up and treatment.

§3-1 entitles the patient to participate in the implementation of his or her health care. This includes the patient's right to participate in choosing between available and medically sound methods of

examination and treatment. The form of participation shall be adapted to the individual patient's ability to give and receive information.

§3-2 entitles the patient to the information necessary to obtain an insight into his or her health condition and the content of the health care, as well as possible risks and side effects.

The legislation is meant to strengthen the trust between patient and physician. A natural interpretation of the concept «necessary information» would be that physicians need to give the relevant information in order to make the patient able to take part in the decision making. This is supported in the legal act preparation texts, in which it is clarified that "the patients must have received adequate information about the purpose, methods, expected benefits and possible risks concerning the current measure"[31].

In my opinion as a clinician, fulfilling this to the extent of its letter would be close to impossible. There is, however, as often with legal texts, room for interpretation. The words "necessary" and "adequate" are the keywords here. The information needs to be limited to what is useful to the patient. The preparatory texts also make it clear that not all conceivable information about the condition and available treatments should be encompassed by this law [31]. Too much information may be disadvantageous and even confusing for the patient.

In §3-5 it is also stated that the information should be adapted to the individual and that the physician needs to make sure that the content has been understood. This legislation places high demands on physicians as communicators; they are expected to tailor their information-giving and the decision-making to the individual patient's background, preferences and perceptiveness[84].

3.2.4. Recall

To evaluate recall of information, we need to define what information is given, discuss how it is transferred to the receiver and find a way to measure what part of it is remembered. These are mainly qualitative entities, which ultimately affects the results and therefore require careful definitions.

3.2.4.1. Communication and information transfer

To communicate is not a one-way process. Without a recipient who has understood the information relayed, the communication has been unsuccessful. There is evidence that patients do not always understand provided information[32, 85, 86]. In a retrospective study in 2004, 27 % of patients who had gone through laparoscopic surgery, did not know or were incorrect regarding the surgical

procedure performed[87]. In Østen's observational study (which was published after our data collection in this project was finished), five of eight observational ward patients who were discharged with more than one change in medication had only partial or no recall of these changes[59].

In this work, the expression "information transfer" is used to describe that a unit of information has not merely been presented by person A, but also been heard, understood and processed by person B. I am not using the expression to refer to any model of communication. So how do we know whether person A has successfully conveyed a piece of information to person B?

We could have person B repeat it back. But even a parrot can repeat words; that does not necessarily mean that the bird has understood the information the words contain.

We could look at the reaction of person B. Biologists in the second half of the 20th century saw communication as an example of cooperation that created a mutual advantage for both parties, when a signaller provided information that receivers used[88]. The assumption of mutual beneficence was rejected by Krebs & Dawkins, (1984), who argued this point down to an average beneficence for the receiver. In 1980, Seyfarth et al. published one of the most influential papers on nonhuman primate communication, showing how vervet monkeys have different warning signals for leopards, eagles and snakes. Each call elicits an appropriate response from other monkeys; respectively leaping into a tree, scanning the skies and looking on the ground[89], which have been interpreted as a semantic understanding of transferred information. It is however a far cry from this animal behaviour to the responses humans would present. Our lives are so complex and the dangers we face are more abstract than just getting out of a predator's way. If we did look at reactions, we would have to see whether the patient, after the consultation, actually changed their behaviour as a result of the physician's information. Humans have an advantage over beasts. We can just ask. Or is it that simple? If we have a conversation with person B about the information relayed from person A to person B, we would get an idea of whether B can relay complex information coherently and logically, which would give us an idea of B's understanding. When measuring recall, we need to see if B is able to place the unit of information in a context to know that B has understood the information given. The measurement we would get of understanding, however, would be limited by B's memory and verbal ability to recount what she had been told.

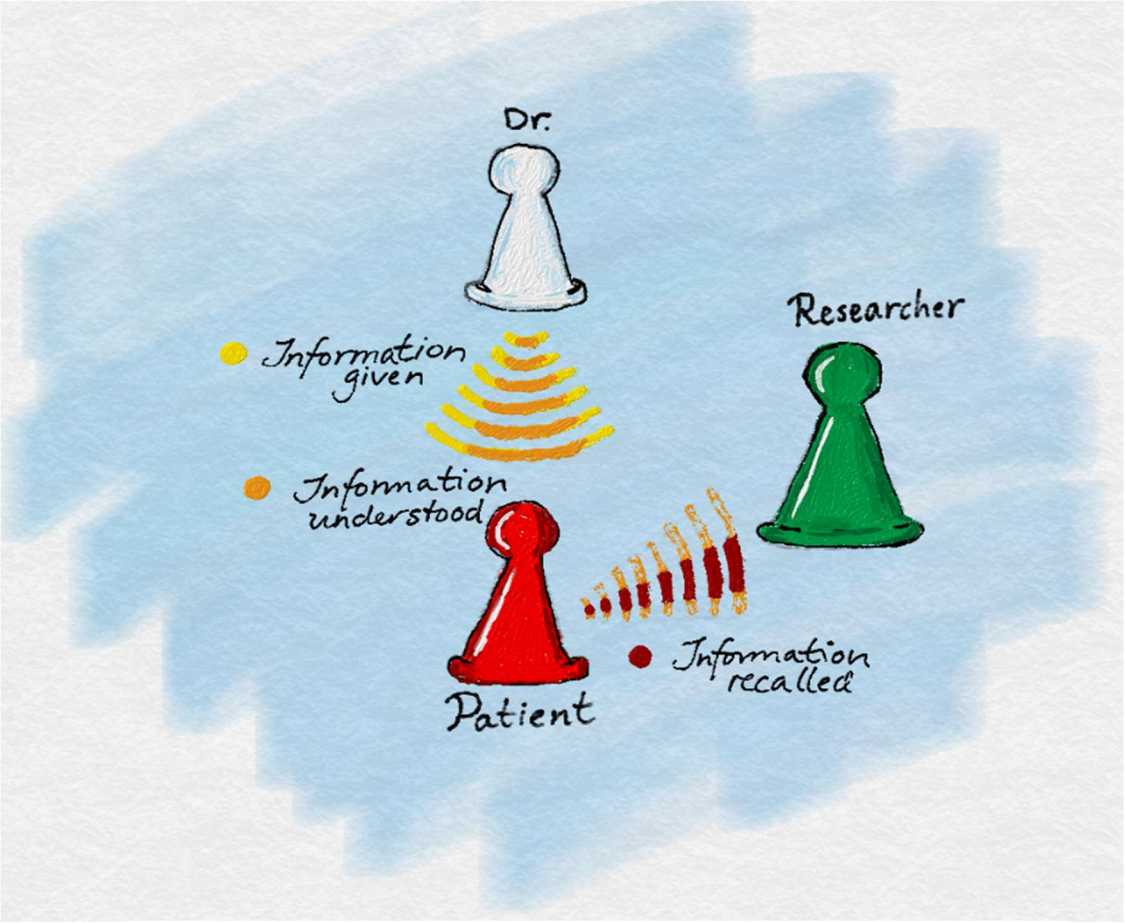

Figure 1. Simplified visualization of information given, understood and recalled.

By measuring recall of complex information in an interview, we measure both comprehension, memory and productive verbal ability. I have not been able to find evidence for a reliable way to separate the three. Figure 1. shows a simplified visualization of information given, information understood and information recalled. The Patient may recall information without understanding it, and repeat that to the Researcher, who will have to judge whether a unit of information is understood based on the Patient's ability to place it contextually. Note that the patient's productive verbal ability is not represented, but one would expect it to influence the proportion of information reaching the researcher as well.

There is still no gold standard when it comes to measuring information transfer [90], so we found ourselves in uncharted territory. This gave ample opportunity for true research, as we embarked on trying to measure something as evasive as conveying unscripted complex information in free speech.

3.2.4.2. Human memory and cues

Declarative/explicit memory are defined as memories that can be consciously recalled, and are stored in the medial temporal lobe, particularly in the hippocampus. It may be subdivided into semantic memory, and episodic/autobiographical memory. Semantic memory recalls facts, and episodic memory recalls events and experiences. Nondeclarative/implicit memories are unconsciously recollected and stores in various regions of the brain according to their perceptual properties. Memories will, however, often be complex and involve multiple memory systems interacting with each other[91]. I am not going to expound the neurobiological mechanisms that underlie the formation and storage of memories any further here, as it is beyond the scope of this thesis.

When measuring memory, we need to know something about encoding and something about retrieval. There is an amazing potential in the human memory. Still, we do forget. It is not known if this means that we discard information deemed unnecessary, or if it is all kept in storage somewhere where we are unable to retrieve it, deep within our brain.

Memory has long been seen as composed by short-term memory (STM) and long-term memory (LTM). The term working memory is by some considered to be synonymous with short-term memory [92], but there are a dozen competing theories[93]. Most consider it a multi-component system, a sort of interface between memory, reasoning and learning[93]. A simple model of memory encoding is that information first reaches the short-term memory, where the working memory contributes with decision-making and problem-solving but also with deciding what is to be transferred to the long-term memory and what is to be discarded. This is a subconscious process, but one that we can consciously affect by focusing hard, rehearsal or making associative retrieval clues. The process may involuntarily be affected by sensory input or emotional input. There are many different models, one of them is called the dual memory theory[92], see Figure 2.

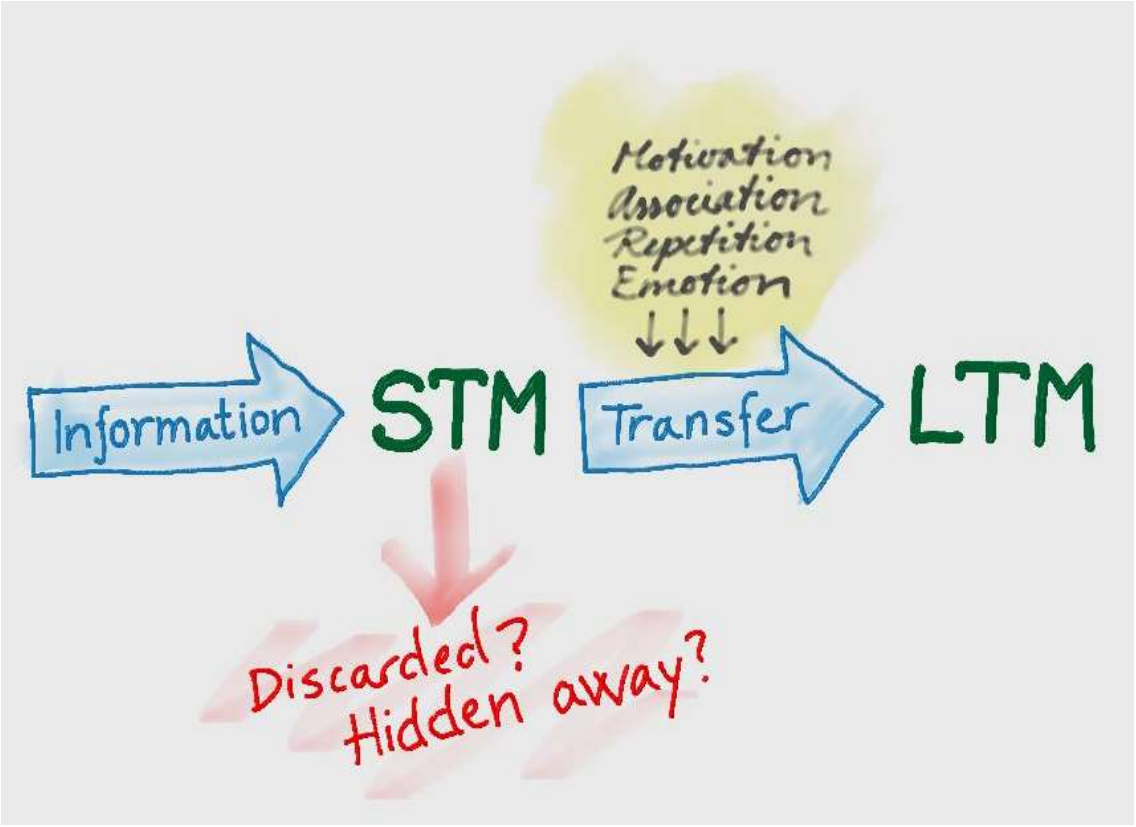

Figure 2. Dual memory theory

When it comes to retrieval from the long-term memory, there have been many attempts through history trying to find the best way to influence people to give their recollections of a past event as flawlessly and fully as possible. One example is The Cognitive Interview, a method comprising a series of memory retrieval techniques designed to increase interviewee recall of something they have eye-witnessed[94]:

1. Context reinstatement – encouraging the interviewee to mentally reconstruct the context of the event (in this case, help the patient reconstruct the consultation with the physician).
2. Report of everything they are able to recall, even if it is partial or incomplete.
3. Different retrieval cues may access different parts of the memory concerning a complex event.
4. More than one retrieval attempts in different temporal order.

Patients have to understand and process several pieces of information for each situation they are presented with. We keep enormous amounts of information in our minds. To retrieve these data

when recollection is needed is a challenge. One definition of the human memory is that it is a joint product of stored memory traces and cues that are available at retrieval[95].“Only a small proportion of all the information we take in is successfully encoded and available for retrieval”[96]. Bjork also describes retrieval of information from memory as “context dependent”. Retrieval processes in the brain are considered to be cue-dependent. Since we wanted the recall part of our study to be as natural as possible, we decided to use prompts and cues during the recall interview.

Definition of “cue” in this context by the Merriam-Webster dictionary:
“a feature indicating the nature of something perceived”.
Synonyms are, among others: clue, hint, indication, inkling, lead.

Definition of “prompt” in this context by the Merriam-Webster dictionary:
1: to cause (someone) to do something
//Curiosity prompted her to ask a few questions.
2: to say (something that encourages a person to talk)
//"Did you hear me?" he prompted when his friend did not respond to his first question.
3: to assist (one acting or reciting) by suggesting or saying the next words of something forgotten or imperfectly learned: CUE

Prompt and cue can both also work as transitive verbs with similar meaning; to signal someone to begin a specific action.

The meaning of these two words is not linguistically crystal clear, as they are used differently by different people and their meanings sometimes overlap. The way I have used them in this work is that a prompt is the general action made to cause a patient to try to recall, like the action of giving a cue. A cue on the other hand includes stimuli that makes one associate to particular memory items. A cue could also be some other aspect of environmental of body-state context, like a certain smell or touch[96]. In this material I have used “cue” for specific verbal stimuli meant to jog the patient’s memory on a certain topic, e.g. «The doctor mentioned some *side effects* to this medication. Do you remember any of them?”

3.3. Current knowledge

When searching for prior knowledge on medical treatment information sharing, I identified three main areas of communication research that deem particular attention: (1) assessment of medical treatment information sharing, (2) interventions to improve patient recall of medical treatment information, (3) the link between communication processes and health outcomes.

3.3.1. Assessment of medical treatment information sharing

3.3.1.1. Assessment of medical encounters

Several researchers have created coding systems for describing medical encounters [97-100], focusing on different aspects, such as patient centeredness [101], patient participation[99], communication competence[102] and relational aspects of the patient-physician interaction [103]. As early as 1950, Bales developed a method of categorizing behaviour observed in face-to-face interaction[104]. RIAS is one widely used, recognized and validated method for coding patient-physician interaction[97]. Each utterance in verbal dialogue is placed in one of 40 mutually exclusive categories, defined by content: task-oriented (asking questions, giving information, counselling) or affective (showing empathy, reassurance etc.). The main data consist of the number of utterances in each category. RIAS can be modified into targeted sub-categories like information-giving about medication.

Substantial research focuses specifically on medical encounter contents associated with medical treatment. The studies explore different aspects, e.g., patient and physician participation and/or concordance [105-109], or factors influencing questions being asked about medications[109, 110]. There are also studies that present comprehensive coding systems describing the content of conversation about medications. Richard and Lussier's MEDICODE is one such descriptive tool dedicated to describing *what* information is discussed about medications[98]. Tarn et al. defined and quantified the different communication aspects they found in 185 physician–patient visits in which new medications were prescribed[100].

To summarize, several researchers have shown that it is possible to conceptualize and reliably score different communication aspects between physicians and patients.

3.3.1.2. Previous studies of patient recall of oral information

Most previous studies have measured patient recall of 20 statements or less, and used recall interviews to determine how much was remembered of the information shared. [111-117]. In Ley and Spelman's study the patients were given about 10 information items.[111-113]. In Joyce's study the physicians also shared averagely 10 items of information. The consultations were tape recorded, transcribed and coded into pre-determined categories. Post-consultation interviews were performed with one of two interviewers first eliciting spontaneous recollections without prompting, then probing into pre-determined categories. The interviewer did not know what information had been given. The information from the examination and the interview could then be compared. Patients remembered about half of the 10 things they were told[113]. Anderson et al. gave a mean number of 12 informative statements in unscripted dialogue. These were recorded by a secretary and recall was procured through a recall interview. Result: 40% recall, 48% misconstrued. The more given, the more recalled, but proportionately less of this was correct[114]. Some studies have taken on higher amounts of information, like Siegrist et al.'s study [57], in which proxy-patients were presented with 42 pre-defined items of information on a discharge video, either structured in different ways or not. Afterwards they were asked to write down what they remembered. In Ackermann et al.'s study from 2017, proxy-patients were shown one of two versions of a video of a physician conveying an identical set of 28 items of information, either structured or nonstructured, and asked to write down what they remembered afterwards[118]. Both these, as well as McCarthy et al. used pre-defined, standardized amounts of information. Bertakis did an experimental study in which less than 14 unscripted information items were delivered. She was investigating whether asking the patients to restate what they had been told, followed by physician correction/repetition, would increase recall. The recall rate increased to 83.5 percent compared to 60.8 percent in a control group in which this technique was not used. Dunn et al. presented unscripted information in their investigation of whether providing the patients with information tapes would enhance recall. Recall was assessed in a structured interview. Average recall for all groups was 6.4 of the 25 items of information presented.[119]. Lipson-Smith et al. also did a study on recall of unscripted medical information, see 3.3.1.3. below [120].

I have not been able to find other previous studies of recall of *unscripted*, *unlimited* information, tailored to the patient's individual needs.

3.3.1.3. Measurement systems for patient recall

Jansen et al. indicated that different recall scores are obtained when using different assessment methods[121]. There are, as shown above, many who have done studies on patient recall of oral information. They have mostly calculated the recall rate in a manner roughly similar to this: The patient is shown a video-tape of a consultation, or an actual consultation is audio- or video-taped. Second, they use different techniques for extracting recall: e.g., interviews that are audio- or video-taped or asking the patient to write down what she remembers[57, 118]. The third important task is to define the information from both of these and compare them. Few go into more detail here than defining countable information as a statement, sentence, idea or speech segment containing a piece of information[111-117]. This seems to have worked with few and pre-defined items. Siegrist et al. had 42 pre-defined items and used two coders, achieving high interrater reliability[57]. Dunn et al. had few items, but unscripted, see above[119]. Lipson-Smith et al. developed a method for measuring recall of unscripted medical information in non- English- speaking patients called Patient-Interpreter- Clinician coding (PICcode), in which they audio-recorded consultations, and elicited free recall by interview. Every unit of medical information in the consultation was identified and categorized in a coding tree. Their method was not unlike ours, however not published until after our own methodology was developed[120].

As described above, many have made tools for categorizing and describing *how* physicians inform patients about medical treatment, and what content they focus on, but no one has to our knowledge yet published a reliable method for investigating recall of complex and unscripted oral information provision about treatment options shared with patients with multiple sclerosis (or any comparable chronic disease).

An effective methodology needs to be developed to measure *complex and unscripted* oral information given and recalled during free dialogue.

3.3.2. Training interventions aimed at physicians for improvement of patient recall of medical treatment information

3.3.2.1. Factors that influence training efficacy

Experience from educational psychology tells us that motivation is an important factor underlying any behaviour change. When a physician is motivated to change, either via intrinsic or extrinsic motivation, effective learning is possible[122].

In 2011, Berkhof et al. did a meta-review of twelve systematic reviews on general communication skills training programmes for physicians. A lack of generalizability stemming from studies having been done on patients with specific diagnoses was noted, as well as grave methodological limitations. It was difficult to compare different training programmes to one another, as no agreement on outcome measures exists. Their conclusion was that training programmes are effective if they are practice-oriented, last at least one day, and use strategies such as roleplay, feed-back and small group discussions[123].

3.3.2.2. Factors that influence the outcome patient recall

A number of studies have shown that patients forget a large proportion of the information they get [49-51, 114]. We know that there are large individual variations in patient recall proportion[124]. Kessels lined up three possible categories of reasons for this in his review*: Patient factors*, like health literacy, IQ, old age, gender, motivation, or disease- or side effect-related brain damage; *Information factors*, like amount, presentation mode or structure; or C*linician factors*, like communication style and use of techniques thought to enhance recall[50].

In a systematic review that includes results from clinical trials that summarize patient and information factors that can influence recall, Stull et al. shows that increased time interval between an event (in this case the physician providing information) and the report of it (in this case the patient telling the researcher about it) seems to imply less accurate recall. Complexity of information has similar effects. Relevance of the information to the patient, on the other hand, has been shown to increase recall[125]. Anxiety levels have shown heterogenous effects[111, 114, 119, 121, 126, 127]. Ley showed that explicit categorization of orally delivered statements led to an increase in recall of medical information[128]. Two more recent studies also suggest that structured information could be beneficial for recall, especially for patients with a low health literacy[57, 118].

3.3.2.3. Training interventions for clinicians, aimed at improving patient recall

Watson et al. did a systematic review of 34 interventions designed to improve recall of medical information[129]. Many of the studies focused on the use of written or audio-recorded medical instructions and are therefore outside our scope of interest. A few papers did incorporate strategies built from psychological theory for oral information giving, like rehearsal, personalized teaching and specific communication styles. Five papers explored information delivery strategies in conversation[130-134]. Isaacman et al. found a significant effect of strategies like “decreased medical jargon, simple language, review of essential information” on recall[130]. Previous observational studies have shown that teachback; reciting information back to the provider, gave significantly higher recall[133, 135], and Bennett et al. also showed that having the patient repeat twelve pre-

decided key points back to the physician significantly improved recall[116]. Gattellari et al. found that shared decision-making had no significant impact on recall[134].

Most reviews on medical information sharing or recall promotion strategies have been focusing either on specific diagnoses, which may imply a reduced generalizability beyond that particular group, or on specific communicative settings; e.g., delivering bad news or decision-making[45, 136-140].

3.3.3. The link between communication processes and health outcomes

In this text, I use "communication processes" as a term meaning different strategies used by the physician that are generally assumed to improve physician-patient communication. In "health outcomes", I include both objective measures of disease (e.g., Expanded Disability Status Scale (EDSS), an effective method to monitor disease progression in MS[141]), other objective measures, e.g., patient recall, and subjective patient-reported measures, e.g., symptoms, motivation or satisfaction, and associated patient-related behavioural outcomes.

Kirkpatrick described a four-level model of evaluating training programs already in 1959, the levels being 1. Reactions; 2. Learning; 3. Behavior; and 4. Results. Evaluation becomes more difficult, the higher the level. A patient outcome would be level 4, while a change in physician behaviour would be a level 3[142].

Levinson et al. describes three levels of outcome that can be evaluated in communication training evaluation: The immediate outcome is improved physician behaviour. The intermediate outcome could be improved patient knowledge, recall, understanding, adherence or satisfaction. The ultimate outcome is improved health[143].

Street et al. uses different descriptions than Levinson in their review about direct and indirect pathways linking communication to improved health outcomes; the latter being split into proximal outcomes, intermediate outcomes and improvement of health[144]. An example of direct pathways would be validation, empathy, touch and support resulting in fewer negative emotions and/or lowered physiological pain/stress. The indirect pathways would take a route through proximal outcomes like patient satisfaction, adherence motivation, trust in the physician and an improved understanding between patient and physician. These proximal outcomes could then affect intermediate outcomes, e.g., adherence, which again could lead to improvement of health. Street et al. did not mention *recall*; however, they have placed *understanding* under proximal outcomes.

Perhaps Levinson's ultimate health outcomes could be shown with large cohort studies, but the confounding factors would be abundant and close to impossible to control for. Interventions that link communication to patient outcomes are rare[145]. Information sharing is linked theoretically to Levinson's "intermediate" or Street's "proximal" endpoints recall and understanding. So many confounders influence the patients' parameters of health. This makes it hard to find evidence for an effect of specific communication strategies on patient outcomes. There are some meta-analyses and systematic reviews that have shown such associations, but the results are ambiguous[29, 146-150]. There is also a lack of agreement on outcome measures in the field[123].

Menichetti et al. recently conducted a scoping review on the literature on verbal information sharing strategies in medical dialogue, listing them in four main categories of experimental studies; cognitive aid, persuasive, relation-oriented, and objectivity-oriented. After applying inclusion criteria, these authors were left with 39 studies to review. They found room for improvement of the methodological quality; both that information on treatment fidelity was reported only for non-RCT's, and that in four of the six non-RCT's reviewed, no action was taken to ensure that the intervention was conducted reliably and consistently. Their findings include a listing of strategies physicians can choose based on which outcome they would like to improve. [140].

Gilligan et al. did a meta-analysis in 2021 on the effects of interventions for medical students that aim to improve interpersonal communication in medical consultations. Overall, they found that interventions had positive effects on most outcomes, but that small effect sizes and evidence quality limited the conclusions that could be drawn. Effects on information giving skills were uncertain (very low-quality evidence). They concluded that future research would be strengthened by more standardized assessment and evaluation of skills[151].

At the time when this study was undertaken, there was a lack of research on how the medical information is provided in real life consultations[2]. To address this knowledge gap, Lie et al. conducted a systematic review investigating the effects of information-giving strategies on patient outcomes. Among the 17 RCTs reviewed, nine studies assessed objectively and subjectively measured patients' behavioural outcomes, and eight interventions reported a significant positive effect[2]. Ten interventions also had patients' recall as outcome. Two of the ten interventions reported significant increase in recall from teach-back[116] and structuring [118]respectively, while letting analogue patients watch videotaped, scripted bad-news consultations containing the same information but with different emotional response from the oncologist, led to significant changes in recognition but not in free recall[152]. Lie et al. found that there was a need for more consistent methodology when testing medical information-giving strategies.

3.3.4. Specific communication processes important to this work

3.3.4.1. To improve comprehension by portioning out the information in instalments

When someone aiming to give information (from now on called the *speaker* in this context) presents information in dialogue, she needs to decide how much to contribute before seeking a response from the person she is talking with (i.e., the *addressee*). Speakers often portion information into *instalments*, inviting addressees to affirm their understanding before going on[153]. The more complex the information is, the shorter the instalments[154]. Speakers can employ strategies *pre-emptively,* that is, before any sign of non-understanding or confusion from the addressee. In experimental work, Svennevig et al. showed that dividing information into instalments was one of several pre-emptive strategies speakers used that enhanced addressee comprehension[155]. The brief pauses between instalments provide opportunities for addressees to indicate that they are following (e.g., nodding, saying “m-hm”), which suggest that addressees are aware that an extended utterance is underway and not yet complete[156]. By using such responses during pauses, addressees claim attention, understanding, and even agreement. However, pauses also provide an opportunity for addressees to show they are not understanding. Svennevig[157] demonstrated that when addressees indicate some trouble understanding, speakers respond by decreasing the length of instalments, presenting information in shorter units and seeking responses from the addressee more frequently. Such evidence supports training physicians to portion complex information into instalments, inviting the patient to provide acknowledgments along the way, or alternatively, to signal problems of understanding that need repair at an early stage.

3.3.4.2. The role of speaker gaze on addressee responses

Research on face-to-face dialogue shows a relationship between pauses in speech and how interlocutors use eye contact: not every pause between instalments constitutes an invitation for the addressee to respond. Research since the 1960’s has demonstrated that speakers invite addressees to respond by looking at them. As early as 1967, Kendon analysed the function of gaze direction in dialogue. His research showed that addressees tended to watch speakers, but speakers transitioned between looking away from the addressee to looking towards. Specifically, Kendon showed the systematicity of addressee-directed gaze, which speakers timed to occur at the end of phrases within longer passages of fluent speech, creating a moment of mutual gaze[158].Bavelas et al.[159] termed these brief periods of eye contact gaze windows and showed how addressees responded accordingly: Speakers opened a gaze window by looking at the addressee, who then supplied a response at a statistically significant rate. Speakers then looked away, closing the gaze window while continuing to

speak. Kendon had posited that this gaze behaviour enabled the speaker to request attention signals from the addressee, thus implicating its role in eliciting signs of understanding from the addressee[158]. Stivers and Rossano proposed addressee-directed gaze as one of four “response mobilizing resources” speakers have in their arsenal[160].

3.3.4.3. The role of instalments and mutual gaze on addressee recall

While previous research had implicated mutual gaze on addressee responsiveness, research in pedagogical fields demonstrated a beneficial effect of mutual gaze upon addressee recall[161, 162], Sherwood implicated attentional factors, finding that when speakers looked at their audience, the auditors were more likely to stay attentive, thus performing better on recall tasks[163].

3.3.5. Knowledge gap

The field is in need of further experimental research for improving recall of medical information in clinical settings. As Lord Kelvin stated in 1883: “If you cannot measure it, you cannot improve it”. With reliable methods for measuring recall as an outcome, and well defined and measurable strategies assumed to enhance communication, trials to assess the efficacy of such interventions in a clinical setting may be undertaken[164].

Previous studies that have endeavoured to measure patient recall of oral information have done this as described above in 3.3.1.3. When sharing *complex, unscripted* information in natural dialogue, people do not express themselves stringently. There are multiple broken-off sentences, pauses, listings, misunderstandings and clarifications. Recall is not just given verbatim, but imprecise; in gist understanding, paraphrases, etc. There is a need for a measurement system that could reliably compare recall in a natural dialogue to the oral information that had been shared. This is our objective with study 1.

Whether training physicians in specific communication strategies for providing unscripted and unlimited complex medical information improves patient-related (Levinson’s intermediate) outcomes remains unproven[165]. In study 3, the objective is to improve recall as an intermediate outcome within a clinical setting by exposing the physicians to a short communication training focusing on known strategies as tailoring, limiting the information amount, checking and making meaningful pauses.

The evidence base is underdeveloped when it comes to the mechanisms and pathways between specified communication functions and concrete endpoints[41]. Whereas study 1 focused on defining and measuring concrete endpoints (the proportion of information the patient recalled), study 2 focused on the communication pathway leading to that endpoint. In study 2, the objective was to use an inductive analysis to describe how physicians use these specific strategies, which was required to measure changes in their behaviour. Multiple studies have pointed out the need for improved methodological quality in research about intervention towards physicians and the evaluation of their outcomes[2, 140, 151].

4. Aims of the thesis

The thesis' overall aims are to define, measure and improve complex unscripted treatment information sharing from physicians to patients with chronic disease facing difficult treatment choices.

The more specific aims of the individual papers are listed below:

Paper I	To develop a method of reliably measuring complex, unscripted treatment information provision and recall.
Paper II	To operationalize three communication strategies and describe how physicians use them.
Paper III	To establish the effect of a short, tailor-made information provision training for physicians on patient recall of complex, unscripted, MS treatment escalation information.

5. Material and methods

For this thesis, all papers are based on data from a randomized controlled study (RCT) testing the intervention of a tailormade training session aiming to improve the skill of neurologists in giving complex information about Multiple Sclerosis escalation treatment choices to Multiple Sclerosis patients. All participants were recruited from the Neurological Department at Akershus University Hospital.

5.1. RCT design

The randomized controlled study was set up as follows: 17 physicians each consulted with 2 patients with MS; one before and one after they had received communication training, see *Figure 3*.

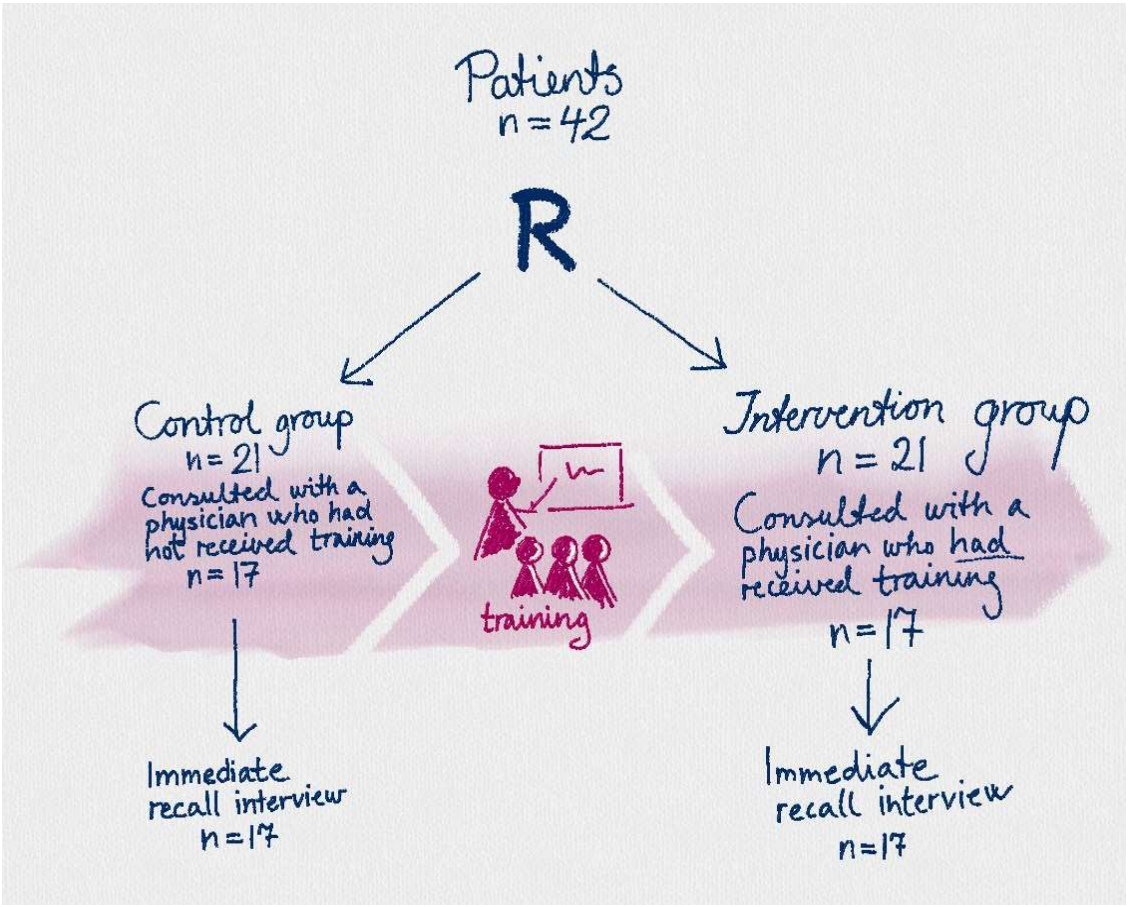

Figure 3. Participant flow. Note how the patients are randomized to the same 17 physicians, but before and after they change their status from untrained to trained.

The 17 physicians received a short training course tailored to the specific situation of informing a patient with MS about a discovery of ongoing disease activity and thus about available escalation treatment options. The training was specifically designed to help them solve this situation as well as possible. The setting in the RCT was a consultation in which the physician informed the patient about a fictive increase of disease activity, informed about treatment escalation options, and advised the patient in the choice of one out of three treatments. The patients were fully informed about the study, the fictiveness of the situation, and blinded to whether they met with a physician before or after he or she had received training.

I performed the immediately following patient recall interview, using a Check List of my own devising, enabling me to make sure that each patient received prompts that reflected the information they had been given. Both physicians and patients filled out questionnaires. All consultations and interviews were videotaped and transcribed verbatim.

The RCT was initiated without a clearly defined main outcome measure, due to lack of previous studies of complex and unscripted medical information transfer in unlimited dialogues. The power calculation was based on the assumption that the training would yield a high effect. We had to develop the measurement scale as part of the project, and therefore the numerical effect size and its natural variability was unknown. We estimated the average effect of the intervention to be similar to the standard deviation of the measured effect. Under standard assumptions of a two-sided t-tests of statistical significance at the 5% and 80% power, this would demand a minimum of 16 patients in each arm of the study.

Specific design choices elaborated on in this chapter:

1. Choice of information
2. Intervention, outcome and randomization design
3. Staged setting
4. Uniform practice in recall interview

1. Choice of information.

First, we agreed that we wanted to look at *complex information in unscripted dialogue*.

In many studies on recall, the patients receive pre-defined videotaped[57, 166], written or audio-recorded medical instructions[129]. Most previous studies are done with 20 or less, often pre-

defined, items of information[111, 113-115, 117], with Siegrist et al. as an exception with a recall study in which 42 items were presented[57]. The ten studies on recall reported on in Lie et al.'s latest review all investigate 28 or less items[2].

With unscripted dialogue, I mean that the physicians were free to choose what information to give, the amount and the level of detail. To investigate how much a patient recalls from pre-defined items of information on a list would not be realistic. We wanted the physicians to have to deal with misunderstandings, information overload, uncertainty in risk/benefit, patient preferences, in short, realistic challenges in a clinical setting[32, 73, 167], that I myself have experienced in my work as a neurologist.

Second, we decided what kind of setting that would meet our needs for complexity.
We chose a setting that would be difficult for the physician as well as for the patient; a patient with MS whose disease burden so far is quite low, receives information about increased disease activity and the need for treatment escalation[168]. The physician presents the three most adequate contemporary treatment options, with their effects and risks. This information is massive, inherently uncertain and partly frightening. We also know that many patients with MS have deficits in basic cognitive processes[169], even though these are likely to be less serious at such an early stage of the disease. Altogether, this means that the information needs to be tailored to the individual[170, 171]. In 5.2 *Training Course* and 5.3 *The fictive clinical case presented to the physician* the setting and the reasoning behind it is described more detailed.

One challenge here, that could encumber some of the physician participants, was their unequal background when it comes to experience with patients with MS. The physicians were all employed at the neurological department at Akershus University Hospital at the time of the study. They vary, however, in knowledge, age and experience. We therefore decided to give all of the physicians an information overview fact sheet; a print-out of facts pertaining to the three relevant treatments, taken from Nevro-NEL, a reliable internet source known and available to all neurologists in Norway. (See 5.6.1 *Information overview fact sheet* for details). The reason behind this was to enable the physicians with less experience with this exact situation to focus on information giving, instead of spending time, energy and concentration on searching the internet or consulting other sources for the correct information they needed to give.

2. Intervention, outcome and randomization design.

The intervention was to train the physicians, and the outcome in the RCT was patient recall. We included 42 patients, of which 34 ended up participating, and 17 physicians.

The link from intervention to outcome was achieved through an untraditional set-up, in which the same 17 physicians each first met with one patient in the control group, then received training, and then each met with one patient in the intervention group, see *Figure 3*.

The physicians are acting as their own controls, similar to an earlier communication study by Fossli Jensen et al.[172] The patients were randomized to meet either a physician who had been through training or one that had not. The training is elaborated on in 5.2, recruitment of neurologists in 5.4 and inclusion of patients in 0.

- The intervention in the RCT study is technically defined as the patient meeting a physician who has been through training, while the control group patients met a physician who had not.
- In paper II, we use data from the RCT study to develop the methodology necessary to observe and measure how the physicians use the taught communicative strategies. We study physician behaviour before and after training, thus evaluating Kirkpatrick's level 3 outcomes[142].

3. Real patients, real physicians - fictive setting

Before starting out, we did a small pilot study in which we videotaped real consultations between patients with MS and neurologists at the outpatient clinic at Akershus University Hospital. Multiple challenges made it hard to get more than a few doctors represented; first, patients with MS are only seen by a handful of specialized neurologists. Second, many of the neurologists had few scheduled out-patient hours. Third, our access to the patient room outfitted with video-equipment was limited. Our planned consultations were often suddenly moved to other rooms, as this specific room also had other equipment needed for certain other patient groups. In this pilot, the patients were in all stages of MS.

In *this* study we needed the patients to be in a very specific stage of their MS development; the exact situation of transition from first-line treatment to second-line treatment. It became clear that it would be difficult to include enough patients, especially as we needed to have them see many different physicians. Even if we had admitted 34 patients who were in exactly the situation our study required within the six months set aside for data gathering, I would not have been able to assign them to my participating neurologists; instead, they would have met any in-house neurologists on

that particular shift that day. Not all of the participating neurologists were on rotations where they would have been assigned these patients during this period of time. I would certainly not have been able to be present at all consultations. In addition, we needed the consultations to be held in a special room with video equipment, which was located in a research facility in a different building than the neurological department, where these patients would have been admitted.
It has been shown that recall of fictitious medical information by volunteers closely parallels recall of true medical information by patients[128]. We therefor found it reasonable to conduct an experiment with a staged setting, and decided to ask patients recently diagnosed with relapsing-remitting MS at our hospital, who were still on first-line or no medication, if they would participate in a fictive consultation, in which a physician would give them information about a fictive increase of disease activity, and engage them in a discussion about treatment escalation.

Based on previous research on motivational influences in transfer, it was likely that since they would receive information that could be very relevant for them in the future, they would be motivated to listen, understand and remember what the physician said[173, 174]. We also thought that they would be able to easily put themselves in the situation of having had relapses, as this is a situation MS- patients usually fear[175].

We designed a fictive case that applied to all the patients, see 5.3[1]. The patients received a letter beforehand explaining the setting[2]. This included asking them to pretend that they had been using dimethyl fumarate for a while, had had two relapses with loss of function the last year and therefore recently had had an MRI of the brain and a blood sample taken, and that they were now consulting a neurologist to get the answers and discuss further treatment. Apart from these uniform details, they were asked to be themselves concerning family, work situation, risk behaviour, fears, eventual child wishes or co-morbidity. The physicians received the same information beforehand about the fictive clinical setting, but with a little more medical detail, see 5.3[1]. They were also given the answer to the MRI and the blood sample (the same for each patient). All participants were aware that the situation was fabricated.

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[1] The fictive case that the physicians received can be found in 5.3. The Norwegian original can be found in the Appendix, part C.
[2] The patient information is not translated to English. It can be found in Norwegian in the Appendix, part C.

4. Uniform practice in recall interview

We took steps to make the recall interview as uniform as possible, while still making sure that each patient was asked about the particular information she had been given. In 3.2.4.1 we describe how the outcome of recall will depend on the individual patient's comprehension, memory and verbal productive ability. As an attempt to reduce the impact of verbal productive ability, the interviewer would not merely tell the patient to recount all that they remembered from the previous consultation. When faced with great amounts of complex information, it can be difficult for the average individual to reproduce details in a coherent manner. To recall, the patient needs to bring the information forward from where it is stored. [176-178]. A more natural retrieval might be achieved by giving the patient cues towards the different parts of the information content[179]. Giving distinctive cues can trigger related memories by tapping a common theme[180]. Previous research on encoding-retrieval have shown that recall is improved by the presence of retrieval cues[178]. Retrieval cues can help to trigger the activation of event-related information and elicit more information from memory than free recall[181]. Research on recall show that the more detailed a prompt is, the more meaningful the cue, which again makes access to the information easier for the subject, resulting in better recall[182]. To give quality retrieval cues, an interviewer needs to be aware of what information the interviewee has been privy to[183]. Based on the research mentioned here, one of the design choices we did make was to make sure the interviewer knew exactly what information had been given, in order to be able to give retrieval cues of high quality during the recall interview. During the physician-patient consultation, I therefore observed in real-time on-screen in the adjacent room, see *Figure 4.*

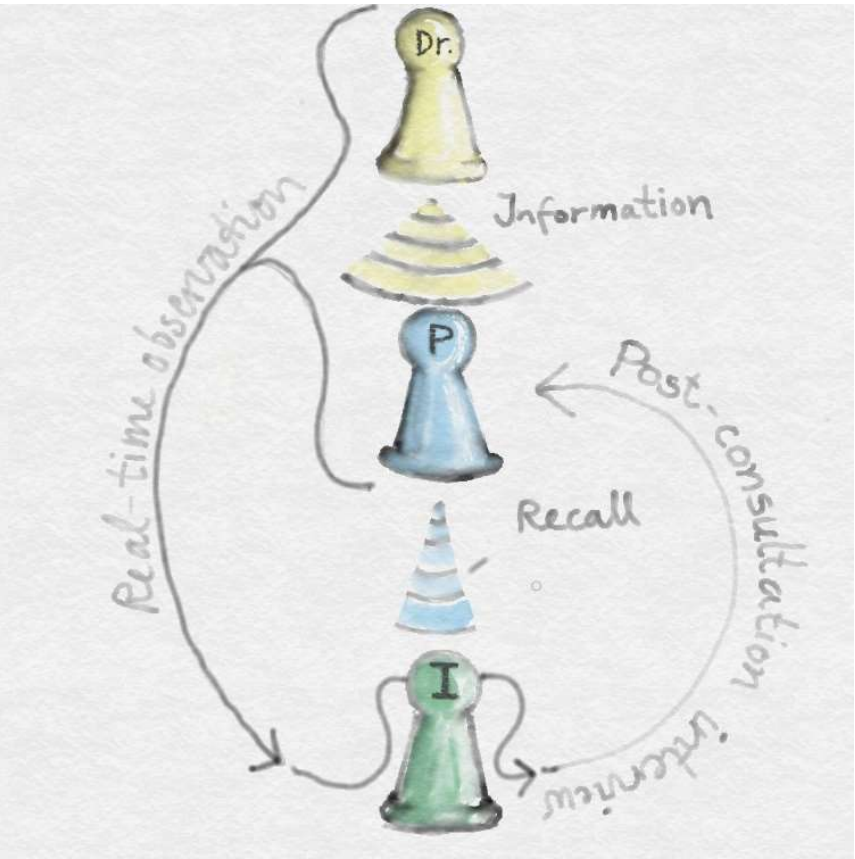

Figure 4. Real-time consultation observation directly followed by interview. (Dr.=physician, P=patient, I=Interviewer).

A study with similarities was conducted by Bertakis in 1977, with the interviewer present taking notes during the consultation[184]. My original plan was to simply take notes, but I realized that with this large amount of unscripted information, I would need to be very organized in order to not miss anything, and to be able to tailor each recall interview to the previous information-giving session. With basis in the information overview leaflets, I developed a Check List[3] of what information the physician had given, see *5.6.5. Post-consultation patient recall interview.* The Check List had ample room for notes. I organized it around the relevant treatments, and then by topic within each treatment.

[3] *The Check List is referred to as "observational sheet" in Paper I, Development of a measurement system for complex oral information transfer in medical consultations. Part of the Check List is included in the Appendix, part C.*

5.2. The RCT training course intervention

Prof. Pål Gulbrandsen, an experienced teacher and researcher of medical communication training, developed and held the specific training course aimed at improving information giving – and recall- in this specific context of a patient with MS needing to decide whether, and with which drug to start escalation treatment.

Prof. Gulbrandsen was previously familiar with a large dataset of video recordings of patient-physician consultations previously collected by his own research group.[185, 186] Unpublished qualitative observations based on these suggest that a situation such as the one we wanted to explore requires that the physician prioritizes and portions the information.

The intervention training course covered the following items, based on existing patient-centered communication theory:

- Mapping needs and preferences in order to prioritize/tailor which information that this particular patient must have in order to be sufficiently informed[187-189].
- Portion: The physician is instructed to use clearer sentences and fewer words, and to pause after delivering information chunks, in addition to allowing a micropause (1-2 seconds) after each sentence to check visually if the patient follows, also providing an opportunity for immediate questions[157, 163, 190].
- Prioritizing/tailoring: During the consultation, assess – given the patient's emotional state, questions and the time available – how much information to provide there and then, and what and when to provide more[191]. Try to limit the amount of information[111, 114].
- Checking for understanding: Has the patient taken in and understood the information that has been delivered[116, 133, 135, 184, 192]?

The training course was a thematically adapted condensed version of patient-centered communication skills[187], with inspiration drawn from the "Four Habits Approach", developed in the US Health Maintenance Organization Kaiser Permanente[193] and "The Expanded Four Habits Model", which was developed especially for patients in emotional distress[194].

In the setting of giving information about escalation treatment options as a response to a new attack, taking the emotional stress on the patient into account is an additional challenge for the physician[127, 195, 196]. A lot of information is needed to make MS treatment decisions. How to convey sufficient information for the patient to be able to do that, while at the same time having an emotional reaction to bad news, is an additional aspect the physician needs to consider. To prioritize

information in order to reduce the amount the patient has to process, is one way to meet this challenge.

Mapping preferences and checking for understanding are elements that are also included in Makoul et al's model of shared decision-making[72]. Mapping preferences is a necessity for tailoring. Patients may not have the same goal as the physician for their treatment[197], and if we want to give them tailored information, we need do know which information they desire[198]. To give tailored information instead of *all* information is also important so as not to overwhelm the patient, as previous studies show that the recall rate is reduced when the amount of information increases[114] Asking patients to repeat treatment recommendations (checking, or assessment of recall and comprehension) has been showed to be an effective method of improving the recall of these prescriptions at the end of doctor–patient encounter[135, 184].

The training was provided three times, in groups consisting of 5-6 physicians, all within a timespan of seven days. It was a 3- hour long course, consisting of equal shares of theoretical instruction and practical training with role play. Examples and practice cases on treatment decision-making in MS were used[199, 200].

The philosophy that inspired this entire endeavor, was that a simple intervention where the physician made these simple and concrete parts changes in their communication could render high effect on patient take-up, understanding, and ability to decide what to do.

The course was deliberately not too time-consuming, for the following reasons: It is difficult to get physicians out of their clinical work, mainly because they have busy schedules and patients will suffer if they are gone. Physicians also tend to work a lot of hours. We had no funds to reimburse them for doing this on their spare-time, and could not expect them to take the time even if we had. There is some support in the literature suggesting that short courses can be efficient [30, 117, 201-206]. On the other hand, a review by Barth in 2011 found that shorter training courses were less successful than longer ones[207]. We hoped for strong results that would help justify implementation of future training on a larger scale.

5.3. The fictive clinical case presented to the physicians in the RCT

The physicians received the following information in advance:

"In this consultation you will meet a real patient with MS, who has not yet received any second-line treatment. The patient has been instructed to use her own experiences and to be herself concerning eventual comorbidity, life situation or problems. The following MS case is fictive and does **not** apply to this patient, a fact the patient is fully aware of. The patient does not possess a complete detailed overview of the clinical history we are giving you, but is aware of the following:

a. He or she has been diagnosed with MS since 2014, but have had previous symptoms.
b. He or she is today taking a medicine against MS called Tecfidera.
c. He or she recently had new attacks, one in February and one in April, which has reduced their level of functioning.
d. An MRI-scan was recently performed, the patient has not yet received the result.
e. A blood sample was recently taken, the patient has not yet received the result.

You are supposed to handle the situation as if it is real for this patient, but not go into details concerning the fictive MS-related clinical history, nor examine the patient.

The task in this consultation is to inform the patient about the results of the tests and discuss the consequences. You are faced with a choice: whether to continue with the same treatment or to choose one among multiple other treatments.

This is the clinical history:

The patient was diagnosed in 2014. It is possible that she had attacks before being diagnosed; in 2008 she experienced slightly impaired function in her left upper extremity, which improved over 3-4 days. In 2012 she repeatedly stumbled and fell while on her evening jog, which she did not think too much about at the time. January 2014 the vision on her right eye turned blurry and a neurological examination revealed a slight ataxia in her right lower extremity. She was successfully treated with Solu-Medrol i.v. MRI investigation revealed eight hyperintense T2 lesions in periventricular white matter and seven in juxtacortical areas, and one gadolinium-enhancing lesion, consistent with demyelinating disease. Spinal tap revealed oligoclonal bands in the CSF, slightly elevated levels of protein, and an elevated IgG-index. She was diagnosed with RR-MS.

Primo March 2014 she started treatment with Extavia (interferon beta -1b) consistent with national recommendations. After each injection she got flu-like symptoms for 24 hours and achy joints for 3-4 days. Since she was clinically quite healthy, she found these side effects intolerable. She switched to

Tecfidera (dimethyl fumarate) after three months on Extavia (June 2014). September 2014, six months after starting with Extavia, a control MRI was performed. It showed some progression, but in the absence of clinical attacks it was uncertain whether the progression had occurred before or after she switched to Tecfidera, and thus she continued on that treatment.

In February 2015 the patient was admitted with an acute MS-attack presenting with numbness and left lower limb weakness. Treatment with Solu-Medrol i.v. had some effect, but a change of sensibility persisted. At the time, it was decided not to change her treatment. In April 2016 she had a new attack which affected her balance and increased the ataxia in her right leg. Her balance remained affected after treatment with Solu-Medrol i.v. A blood sample including JCV antibodies was taken, as a treatment change seemed to be indicated. She was also referred to another MRI. She will receive the results today.

The MRI shows two new periventricular T2 lesions, and one C2/C3 level spinal cord gadolinium-enhancing lesion. There is every reason to think that Tecfidera is working sub optimally, and you are going to discuss a treatment change with the patient today.

Complication: the patient has JCV antibodies with an index of 0.8."

The original case can be found in Norwegian in the Appendix, part C. We designed the case in order for the information to be complex. Therefore, we wanted it to be medically defendable to choose all the three options; natalizumab, alemtuzumab or fingolimod, depending on patient preferences.

Initially we had four options, that the patient stayed on dimethyl fumarate, or that the treatment was changed to either natalizumab, alemtuzumab or fingolimod. The first choice would be less advisable medically, but a physician might allow it to be an option for a short time while the patient took time to deliberate more thoroughly. When proceeding with the study it became clear that the physicians did not spend time on informing the patients about dimethyl fumarate, and to simplify the analysis we decided to not include it in the recall accounting.

At the time we carried out this study, natalizumab had a definite edge on the last two options. To make the options more equal, we let the physician give the patient the news that the patient had antibodies to the John Cunningham virus (JCV) with an index of 0.8, a detail that would increase the risk of a dangerous side-effect[208]. This made individual patient preferences, e.g., for risk-taking, an important issue.

5.4. Recruitment of neurologists in the RCT

We presented the study for the neurologists in the neurological department of Akershus university Hospital, and asked them to participate. The 17 participating neurologists were fully informed about the study, and knew that they met real MS-patients who role-played being in a situation they expected to encounter sooner or later as their disease progressed. Beforehand, they received a letter containing information about the patient framed as a journal exempt, with previous exacerbation history, results of a recent MRI-scan showing new lesions and a JCV antibody index of 0.8, in addition to a more detailed description of the attacks than the patients got: reduced sensory and motor functions in the left leg in February, and increased ataxia right leg with balance problems in April. The physicians were also told which and how few details the patients were given and asked not to go into details about previous or recent clinical findings or attacks, nor to examine the patient. See Appendix.

Recruitment challenges:

- Each physician was to first meet with one patient. After this, the physicians needed time off to participate in one of the training courses, that were held in three groups, at three settings, all within a fortnight. Then they were to meet another patient each. During all sessions the neurologists had to be relieved of their hospital work, which was a challenge.
- All the physicians had some experience with patients with MS and decisions regarding escalating treatment, but MS-care is becoming increasingly specialized, and is concentrated on ever fewer hands. Not very many of the neurologists at the department had extensive experience with this exact kind of consultation. The feeling of not being used to the task at hand may have caused insecurity and made some hesitant to participate. Quite a few did not wish to participate just because they did not want to be video-recorded.

5.5. Inclusion and exclusion of patients in the RCT

All 42 patients were included between April 12.-May 2., 2016 by telephone. I found the patients on a list of multiple sclerosis patients who had been diagnosed at the neurological department of Ahus between 2009 and 2012. We included only patients aged 18 or above. All patients that had started what was at the time called second-line treatment were excluded from participation. All patients listed with primary progressive MS or secondary progressive MS were excluded. An overview of this process can be seen in table 1. A statistician blindly randomized the 42 patients to an intervention group or a control group. One withdrew from the intervention group. We invited 17 from each group to participate in the study, and sent each a letter with a date for their consultation, case information and a map over the hospital so as to easily find the communication lab. Three patients in the intervention group and four in the control group were asked to be in reserve in case of cancellations, and were sent a special letter about this.

Year of diagnosis	N	Patients without enough information (n)	Patients who met the inclusion criteria and who I tried to contact (n)	Patients reached (n)	Declined (n)	Accepted (n)
2012	57	3	27	20	2	18
2011	37	1	8	8	1	7
2010	29	1	15	12	4	8
2009	32	3	15	13	4	9
09-12	155	8	65	53	11	42

Table 1. Inclusion of Patient participants

Most patients were very positive when contacted, and 79% wished to participate. Those that declined generally mentioned reasons like finding it difficult to be away from their workplace or living too far away. Finally, 34 Norwegian-speaking patients with MS currently on no or first line treatment participated in the study.

5.6. Clinical consultation and post-consultation interview in the RCT

5.6.1. Information overview fact sheet

Drawing on my background as a neurologist, I knew from experience approximately what topics a physician would make sure to cover in such an information-giving session. A neurologist who works with a lot of different types of patients would have to do some research to be able to give this information, either in advance or during the consultation. I knew where the neurologists at my clinic would look for information, mainly updated and nationally accepted web-sources of MS-info; Nevro-NEL, Helsedirektoratets retningslinjer and Felleskatalogen.) To even out the playing field somewhat between neurologists who had a lot of experience with these MS-treatments and the ones who had less so, and make it easier for the latter to focus on the information giving instead of on finding the right information themselves on-line, I recapped information about the four relevant treatments from these web-sources in leaflet style, and made them available off-line in a laminated version to all physicians during the consultations, see the Appendix, part C.

5.6.2. Equipment

All consultations and interviews took place in a communication observation lab inside the hospital, with state-of-the-art video-recording equipment delivered by Noldus Inc., Wageningen, the Netherlands. The video-recorders are unobtrusive, looking a little similar to lamps. They enabled recording the same scene from two different angles simultaneously, providing a recording of the faces of both physician and patient. This equipment is provided by the Institute of Clinical Medicine at the University of Oslo.

5.6.3. Questionnaires

As a secondary outcome of the RCT, reported on in paper III, we let the physicians and the patients answer questionnaires concerning communication skills, preferred roles in health-care decision-making and shared decision making. Previous research on patients with MS has shown that being well informed improves adherence[209], and also that autonomy in treatment options is positively associated with treatment adherence[28, 210], however we have not found studies connecting these Kirkpatrick level 3[142] outcomes to recall. As we developed new methods on assessing the amount of information shared with and recalled by patients, as well as methods on assessing physician information-sharing behaviour, we were interested to investigate whether any changes that we found in physician behaviour could also be reflected in previously recognized questionnaires.

- Control Preference Scale

  The Control Preference Scale was developed by Degner et al. to measure “the degree of control an individual wants to assume when decisions are being made about medical treatment." We used the same three parallel statements for three versions of the CPS as Janz et al. [211], translated into Norwegian by JN and translated back as control by Angela Labberton. The patients answered one part before the consultation, and both physician and patient answered after the consultation. The Control Preference Scale has been shown to be clinically relevant, easy to administer, valid, and a reliable measure of preferred roles in health-care decision-making. [Degner, Sloan et al. 1997. The Control Preference Scale].

- Four Habits Patient Questionnaire

  4HPQ is a patient-reported questionnaire of doctors’ communication skills, that was developed from a 23-item patient questionnaire related to the Four Habits Coding Scheme (4HCS). 4HPQ h includes 15 items on physician behaviour with a four-point response scale of ‘definitely yes’, ‘somewhat yes’, ‘somewhat no’ or ‘definitely no’[212]. All patients filled out the questionnaire post-consultation. 4HPQ has been shown to have limitations: patient assessments have not been in agreement with expert observers[213].

- CollaboRATE

  A measure on shared decision making reported by the patient, which takes less than 30 seconds to complete[214, 215]. CollaboRATE has been shown to provide good validity and reliability scores to measure shared decision making and decisional conflict in other contexts[216-218]. All our patients filled it out post-consultation.

5.6.4. Physician-patient consultation and interview logistics

All patients were asked to arrive 15 minutes before the consultation were to start. A secretary met them, and they signed a consent form and answered the first questionnaire: Control Preference Scale. All documents were filed in a separate folder for that patient, marked with a number. Once the neurologist was ready, I would start the video-recording from the adjacent room and the patient could enter.

I would be in the adjacent room, observing the dialogue in real-time on a screen in an adjacent room, taking note of which information was given, on my predesigned Check List, see figure 5. While watching the physician-patient consultation in real time, I checked the topics they covered, checking and/or underlining specific information the physician mentioned, and crossing out information she did not. I also added quick notes of specific numbers or other information not already covered by the Check List.

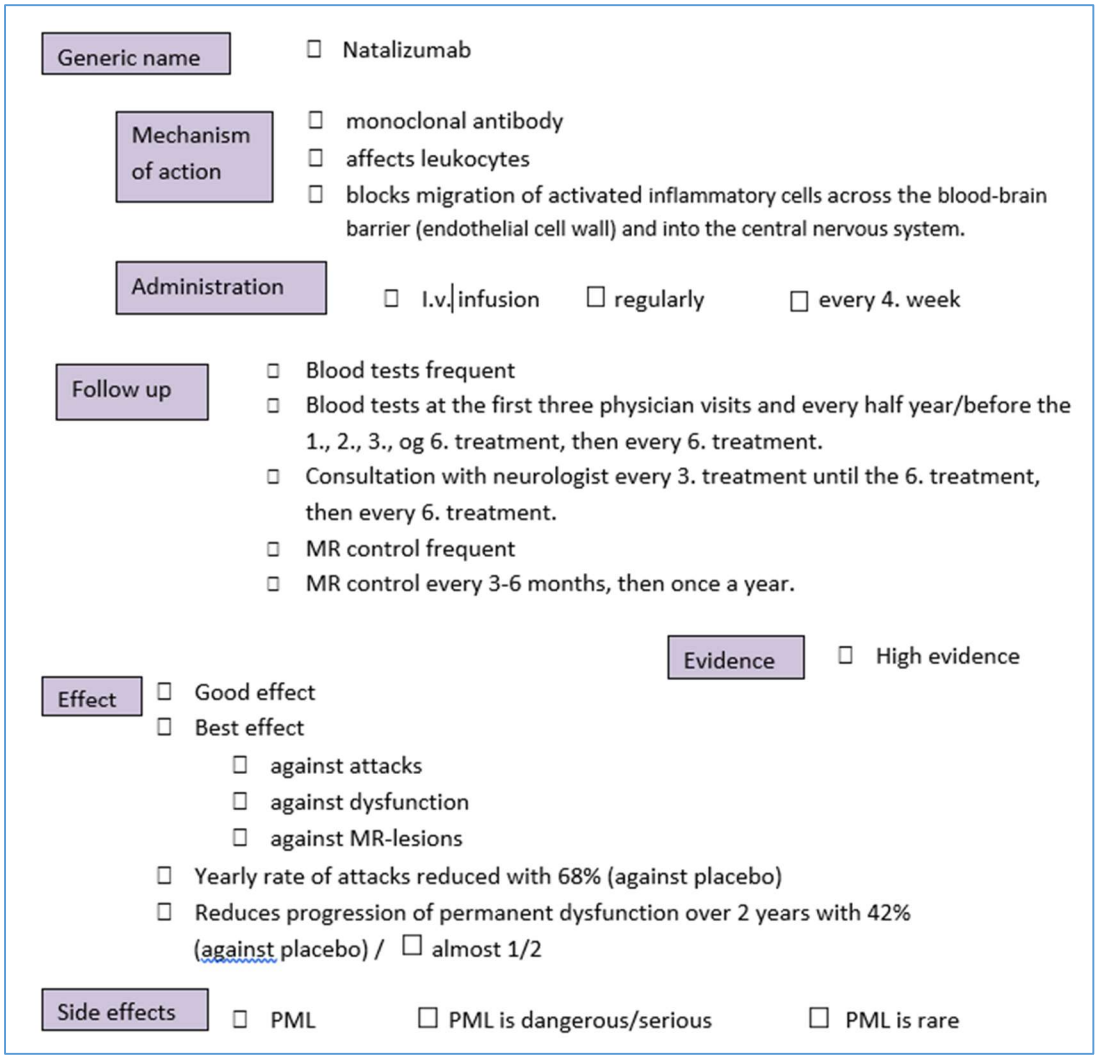

Figure 5. A small cut-out from the Check List translated to English. The original complete Check list for all relevant treatments can be seen in the Appendix, part C., in Norwegian.

Neurologists had 20 minutes at their disposal to inform the patient about the Multiple Sclerosis disease having progressed, the JCV positivity, and of the relevant treatment options; how these would affect the daily life of the patient, and of their risks and effect. After 18 minutes, the secretary

would discreetly remind the physician that it was two minutes left. There was no absolute rule, but the physician had been told to try to keep the consultation to 20 minutes. There was no further interruption if the time limit was exceeded. Encounter duration was measured. Once the consultation was over, the physician would leave the room and answer the CPS questionnaire outside. The questionnaire was put in the patient's folder.
I would now enter the room, with the same video-recording still running, and perform an immediate recall interview. After 18 minutes, the secretary would discreetly remind me that it was two minutes left. After the interview the patient was offered a beverage and a break before answering the rest of the questionnaires; CPS, Four Habits patient Questionnaire and CollaboRATE.

Logistic challenges:

- I needed to personally watch all consultations simultaneously, and perform the post-consultation recall interviews. It was complicated to get the specific physician off hospital work for half an hour at the same time as we had access to the room with video equipment, the patient and myself.
- It was also difficult to get time off for entire groups of physicians to do a half day training course. This got worse as it coincided temporally with a national-wide hospital physician strike, in which the hospital forbade us to do any kind of activity including physicians on their grounds. We had to rent a location outside the hospital, which increased the time-span away from hospital work for the physicians.

5.6.5. Post-consultation patient recall interview

My interview was organized in the following five parts. I did not read the questions verbatim, but freed myself from the manuscript. I kept the interview guide in front of me next to my Check List to make sure I did not forget any of the points.

1. Orientation

Information about the content of the interview:

-Discussion about the previous consultation

-Patient thoughts and reactions

-How much of the information is remembered?

Information about length: up to half an hour.

Information that the interview is being videotaped.

2. Caretaking

Mapping of any troubling reactions.

Information about where to turn if a need to discuss reactions or troubling thoughts should arise at a later stage.

3. Open questions

Open questions to create a safe atmosphere, and out of personal interest, concerning how the patient felt about having to relate to different treatment options, what they found most important to them when weighing the options, if they felt insecure about having understood everything, and how they felt about the law demanding physicians to inform the patients enough to be able to participate in choosing their treatment.

4. Recall part

During the recall part of the post-consultation interview with the patient, I had the Check List in front of me. I asked the patient about the information he or she had just been given, using the Check List to frame open questions about the information the patient had just received.
Thus, the recall part of my interview would be different for each patient, depending on which information the physician had given. I started out with very open questions for each topic, and went more specific as we moved along, in a funnel-shaped manner[92]. I was consistently trying to get as accurate a response as possible by giving thematic cues to jog their memory retrieval without giving hints, taking care not to put words in the patient's mouth. It was easy with a glance on the Check List to see what the physician had said about a specific medication, and which topics about this medication they had covered. An example: The patient tells me in the interview that Lemtrada may have side effects affecting the thyroid gland, but that it was treatable. Then I could ask the patient: "Did the physician say anything about how this could be treated? If one got that side effect?", knowing from my Check List that the physician did in fact give that information. When one topic had been thoroughly covered, I started on a new topic with the same funnel-shaped hierarchy.

5. Closing

I asked all patients the following question out of professional interest: "As a patient with MS, which situation do you find to be the most challenging when in contact with the health services?"

I gave the necessary information about post-interview questionnaires. I also informed about an out-patient nurse contact if questions should arise about the patient's own disease and treatment after partaking in the study. The patients received a repetition of the information already given concerning the fact that the situation is fictive, that the information given in the consultation is not personally adapted to the patient in their real situation, and that they should relate to their own neurologist concerning treatment. Finally, I thanked them for their participation.

5.7. Ethics

The project received ethics approval from the Data Protection Official for Research at Akershus University Hospital and have been performed in accordance with the ethical standards laid down in the World Medical Association Declaration of Helsinki and its later amendments. Sensitive data were protected by maintaining the Akershus University Hospital code of conduct in respect of storing data only within specified permitted access drives and using encrypted hardware.

The Regional Committee for Medical and Health Research Ethics (Southeast Norway) decided that this experiment is exempted from review. Date: March 24, 2015. Reference # 2015/161.

All participants were provided with information about the study orally and in writing prior to giving their written consent. Consent was given prior to inclusion in the study.

Considering that the project involved informing real patients with MS about medications and risks related to a later stage of their disease, we involved Reidun Førde, professor of medical ethics, and a patient representative[4] in the developmental stage of the study. We discussed the ethical aspects of including patients with MS in a study where they receive information concerning a treatment choice that do not really apply to their situation in real life (IRL). There was a possibility that emotional reactions could be triggered. One ethical consideration was the potential damage we could inflict on the patients vs. the potential usefulness this research could have for this patient group, and society as a whole.

The setting we chose had some likenesses with improvisational theatre or live action roleplay (LARP); a form of **role-play** where the participants pursue goals within a fictional **setting** represented by real world environments while interacting with each other in character. In LARP many topics can be introduced that can inflict disruption to emotional and psychological well-being. To design live action role-playing ethically the emotional and psychological safety of the participants need to be managed; this can be done by pre-informed consent and transparency, monitoring during the ordeal, and an

[4] *The patient representative wishes to remain anonymous. S/he did indeed have multiple sclerosis, and was active in the MS Society of Norway.*

offer of aftercare[219]. This inspired how we designed our setting, in order to manage reactions in a good manner:

1. Transparency. One important ethical detail in our design was that the patient participants were informed of what they were going to experience, and gave their consent to this in advance. The material could thus be anticipated. In LARP design this is called “ongoing transparency” and implies that undue deviations from the content warnings of an event are avoided by the organizers[219]. When the recall interview started, the interviewer meta-communicated, that is, informed the patient of what the interview would consist of, to create safety and professional trust[92].
2. Monitoring. The patients were watched on screen by a neurologist during the entire experience.
3. Aftercare. Part of aftercare is debriefing. In LARP this is a structured conversation about the experience, usually held immediately after a LARP[220]. In training simulations it is recognized that there may be psychological and formative need for assisting a person in their transition back to their IRL identity[221]. We chose to incorporate this in the post-consultation interview. We asked the patient how they had experienced the participation. We reminded the participant that the experience had not really been about them as a patient, that the physician’s advice was not in fact aimed at their medical situation, and that they should follow the advice of their own neurologist. We also offered up contact information in case emotional issues were to arise after participation in the study, ensuring that medical advice or psychological support was provided in case of need.

We did a pilot trial June 27., 2016 with Pål Gulbrandsen acting as the physician, and our patient representative[1] as the patient. We rated the risk of serious reactions as low. Our patient representative found the study potentially useful for improvement of communication between physicians and patients in this patient group as well as for patients in other fields of medicine. Feedback was received and used to improve logistics.

5.8. Coding Guide development (Paper I and III only)

5.8.1. Coding group

We were three people in the coding group; Pål Gulbrandsen, Magne Nylenna and myself, Jenny Nordfalk. Pål Gulbrandsen is a specialist in General Practice and Public Health, professor in Health Services Research at the University of Oslo, and a senior researcher at Akershus University Hospital. Magne Nylenna is a physician, journal editor and professor of Social Medicine at the University of Oslo and Norwegian University of Science and Technology. I am a specialist in Neurology and Consultant Neurologist at Akershus University Hospital.

Pål Gulbrandsen had seen many of the videotapes that the transcriptions we worked on stemmed from. I performed the patient recall interviews, and put the units of information into Excel for further coding. Magne Nylenna was given status as a blinded coder, as an external researcher he would be completely unaware if a transcription were from the control group or the intervention group. He would in this status also have the last word in any analytical disagreement.

We had multiple meetings during the development of the coding guide.

5.8.2. Coding group meetings

Meeting #1. In our first meeting all three of us had prepared by doing individual pre-analysis on 5 transcriptions with variations between physician age and experience. As previously covered in 3.3.1, previous coding systems did not meet our goal to measure the amount of complex oral medical information given and recalled in an unscripted dialogue between physician and patient. We did not have predefined “items of information[57]”.

We therefore decided to approach the problem from the ground up. We discussed classification, how to limit the unit of information, and the scoring system. All participants brought valuable thoughts to the table on how we were to categorize the huge amount of free speech we had accumulated in our videos.

In 3.2.4.1, I introduced the concept “unit of information” (UoI). Language, like all signals, need to be parsed into components to be understood by the addressee. Any measure of information depends on how we choose to segment it[88]. We found that one of the largest challenges was how to define a UoI. We came to the conclusion that we needed to define as small units of information as possible, to be certain that we caught them all. This was done similarly by Dunn et al.[119] who defined a unit of information as “a segment of speech from a physician expressing a single idea concerning medical

issues" in their study of whether individual audiotapes of a consultation would increase recall 4-20 days later.

We made the following decisions:

1. To develop a coding guide.
2. To only study information related to the three medication options.
    - Reason: we needed to limit the sheer amount of information units, considering the extremely large material.
3. To classify and give points to the information given by the physician first, before evaluating the corresponding recall interview.
    - Reason: We found it appropriate and convenient to consider the latter a fraction of the former.
4. To not grade importance, clarity, correctness or quality of information.
    - Reason: Our goal here is not to make quality assessments of the information given by the neurologists, merely to measure the percentage of UoI's remembered. We decided that even if the physician informs falsely, it is still information, and will be counted as such.
5. One UoI would count as one point. If the same utterance contains more than one piece of information; more than one UoI, there would be multiple points earned.
    - Reason: The other option was to construct packages of information. This may have been appropriate with a limited number of pre-decided information packages, but was deemed inappropriate when handling unscripted and large amounts of information.
6. Sometimes we suspected that the patient already knew the information. We decided to still count the UoI for the physician, as well as for the patient.
    - Reason: This turned out to be very rare, and difficult to be sure. We are not investigating what the patient knows about the medications beforehand, but what the patient recalls from the consultation. If it occurs, the physician gets 1p and the patient 1p, so it would not affect the recall rate much if the physician instead got 0 and the patient 0.
7. When evaluating the recall interview, we decided that a UoI that was correctly remembered, but not connected to the correct medication, would not be counted. Still, if the interviewer could

infer contextually that the patient connected the UoI to the right medication, but could not remember the name of the medication, the UoI was countable.

- Reason: We wanted to avoid cascade flaws. To not remember e.g., a name, should not automatically render everything else the patient remembers null and void. Still, a recollection of an information unit needs to have a reference frame to be valid.

8. If a UoI was given by the physician during the consultation, but the patient was not given any opportunity to recall it during the recall interview, the UoI would not be counted for the physician either. We decided that a general prompting; giving the patient space and opportunity to expand on a topic/subject, would be good enough.

    - Reason: We see that this was a weakness in the method, but could not come up with a better way to adjust for such phenomena. In retrospect, it did not turn out to become a problem, much due to the great efficacy of the Check List used by the interviewer.

9. UoI's in the recall interview concerning information that the physician has not given will not be counted.

    - Reason: We are not investigating what the patient knows about the medications, but what the patient recalls from the consultation.

In August 2017 we picked five random consultations and each coder coded based on the first draft of the code guide. We then met regularly, going through the material, discussing all incongruences, thus identifying problem areas that needed further regulation. We reached our decisions through group discussion, gradually refining the analysis criteria until we achieved consensus. We repeated this process with coding separately based on the rules we had defined, and for each meeting we revised the criteria in order to make the coding as reliable as possible.

In between, I was working on the guide. This included a process of extracting and organizing all utterances containing units of information pertaining to the three relevant medications.

Meeting #2: We discussed internal consistency, clarity, completeness and repetition.

We made the following coding decisions:

10. We will strive for a maximization of the information-elements.

- Reason: We found that it was easy and time-saving to create information packages, and needed to make this a rule to be able to achieve the same practice.

11. Concerning faults made by the interviewer: If the researcher inadvertently reveals an answer, the UoI will not be counted for the physician nor for the patient recall.

12. Corrections: If the physician corrects her own information, the last chronological UoI will be the one that we want to check if the patient can recall. Only one UoI will be counted for the physician part.

Meeting #3. Discussion of the difference between gist understanding and perfect understanding.

We discussed what level of precision would be adequate to expect. We decided that the patients should not be required to recall each UoI ad verbatim for the recall to be counted.

With "gist" understanding we mean getting the general idea of a concept, without necessarily understanding every detail. Sometimes the physician will list a number of details; e.g., five possible side effects. The patient will recall a general overview; e.g., "there were a lot of side effects". This capacity of generalizing information is something we all do unthinkingly on a daily basis. We do not remember every single car in the morning rush hour, we remember that it was heavy traffic. Supposedly this is an effective integrating mechanism for avoiding overstimulation.

The doctor lists specifics, the patient remembers a general overview. This we do, unthinkingly, all day.
If the doctor lists five side effects, and the patients says: well, there were quite a few side effects", should she get a point? We decided that she should, compared to the patient who couldn't remember anything about side effects.

13. Decision: We would make rules that took "gist understanding" into consideration.

- Reason: It is probable that a physician will express herself with more precision than the average patient when describing medical treatment. It would not be fair to hold the patients to the same standard. Likewise, if the doctor lists five side effects, and the patients says: well, there were quite a few side effects", our reasoning is that this patient recalled more compared to the patient who couldn't remember anything about side effects, and that this needs to be mirrored when counting the UoI's. To accommodate for this less

mathematical, but more qualitative view on memory function, we saw a necessity for working out rules in our code guide that covered this phenomenon.

Meeting #4. Another challenge was the conflict between striving for as many and as small UoI's as possible, and the fact that many physicians would use more than one word to describe a state. One physician would for example say: "Tired and under the weather and feeling beat." [From Norwegian: "Slapp og utilpass og slått ut"].

14. Decision: These three descriptions are of such similar content that they should count as only 1 UoI altogether.
    - Reason: The point is not to check if the patient remembers the exact words the doctor utters, but to measure how much of the gist of information that is transferred and remembered.

Meeting #5. The concept of gist understanding led to a new insight: that there would be a whole lot of interpretation discrepancy between different coders, perhaps with culturally different backgrounds etc. How much is good enough? Sometimes patients remember detached fragments of the conversation, sometimes perhaps just a word, perhaps mixed with details and interpretations they themselves may have attributed to a topic based on their own horizon of understanding. We solved this by adding three more rules:

15. An information unit must be remembered in a minimum of context to be countable.
    - Reason: Sometimes patients remembered e.g., a side-effect without being able to attribute it to one of the drugs. We needed to be sure that the recollection was linked to a context.
16. When in doubt, be liberal in favour of the patient. When the patient recalls, the words will often be somewhat rephrased, generalized and altered[125]. If the coder's interpretation is that the patient has grasped the message and is able to rephrase it, we give points liberally.
    - Reason: Our theory during this RCT has been that the physicians in general give too much information. To ensure that we do not design the measurement tools to reinforce our own prejudices, we wish for the coders to be liberal towards the patient.

17. The physician may only receive points for the parts, the UoI's, not in addition for the whole. This rule is also in effect for "if-then" expressions. The patient can get points both for the whole without remembering all the single parts- and points for each UoI. We decided, however, that a patient point would only be awarded for a recalled common denominator as long as not more than two individual items from a list were also remembered.

    - Reason: We made this decision because of a necessity to reward both the recollection of an overview as well as of details, but without giving double points.

18. The patient would not be awarded points for producing information in the recall interview if the information was not provided by the doctor during the consultation; the information was attributed to the wrong drug by the patient, or if the patient was clearly guessing.

5.8.3. Coding the material

To ease the burden for the coders, I put together an excel-sheet for each interview, with all UoI's about medication given by the physicians. This was the procedure we followed:

Method:

1. Consultation physician-patient. Video-taped. Physician has access to information about Lemtrada, Tysabri, Gilenya and Tecfidera.
2. Post-consultation immediate patient recall interview. Video-taped. The interviewer has observed the consultation in real-time and made a check-list that is used for prompts.
3. All video-tapes were transcribed verbatim.
4. All utterances containing information about medication were color-coded according to the three relevant medications; Lemtrada, Gilenya and Tysabri. If doubt, they were filed under General. This was done in MAXQDA[222], and enabled extraction to excel by headline.
5. An excel sheet was prepared with four different headlines in the left column; General, Lemtrada, Gilenya and Tysabri. The utterances by each physician containing UoI's was organized here.
    a) The researcher organizes utterances containing the same, similar or related UoI's next to each other in a cell(excel) or group, placing the cell under the respective medication's headlines. Absolute duplicates are deleted.

b) The researcher duplicates information that may apply to more than one medication in one and the same sentence, placing the duplicates under the respective medication headlines. The part of the sentence one wishes to count is highlighted.

c) The part of an utterance that is desirable to count, the UoI, is highlighted (in «bold» font). Parts that are counted under other headlines may be put in parentheses. The same sentence may be placed in the cell underneath as well, but then with the opposite parts highlighted/put in parentheses.

Example:

- In one row attributed to the physician under the headline GILENYA, it says:
  «The most common side effects, if you are on Gilenya: well, **that is headache, influenza, you can get diarrhoea**, (and you can get elevated liver function tests). »
  -> 3p
- The next row attributed to the physician under the headline GILENYA, says:
  «The most common side effects, if you are on Gilenya: (well, that is headache, influenza, you can get diarrhoea), and **you can get elevated liver function tests**. »
  ->1p
  Reason: Avoid counting one UoI twice, but still keep the context. Be able to more easily couple UoI's from the physician with respective UoI's from the patient in a neat manner, making the coding neat, accessible and coherent for the coder.

6. Each coder received the excel-sheet with the physicians' information-containing rows of utterances organized by medication. The coder seeks to identify and count all unique and meaningful units of information presented by the physician, using the rule-set outlined in Count-COPIN (Counting Complex Orally Provided Information). The coder is asked to make three decisions per row:

   - Decision 1: Is there any USEFUL information in the row?
   - Decision 2: How many UNITS of information are in the row? (Probably one or more)
   - Decision 3: How many UNIQUE UNITS are in the row?
     - Compare to previous units of information in the *same* row: Are any of the units of information just repeating something that has been recorded already? Check with the rules above.
     - Compare to previous units of information in *previous* rows: Are any of the units of information just repeating something that has been recorded already?

   Result: Number of unique information units.

7. Each coder went through the recall interview transcript, seeking to identify, match and count all unique and meaningful corresponding units of information recalled by the patient, using the rule-set outlined in Count-PROPIN (Counting Patient Recall of Orally Provided Information)., making three decisions per UoI:

    - Decision 1: is there any relevant information here?
    - Decision 2: Refer both to the excel file and the interview transcript to catch anything that is unique information from the patient that matches unique information from the doctor. Circle in the interview and give that circled information the same code as in the excel rows with the doctor information.
    - Decision 3: Double check everything that the doctor said that the patient doesn't say to ensure you haven't missed anything. Note whether the patient has received prompt or space to voice their recall.

8. Each coder scores 1 point per UoI for both physician and patient, following the rules of the Coding Guide. Exemptions for gist understanding.

5.8.4. Inter-rater reliability

We made a reliability sample for coding. The reason for this was to get a quality indication of the codebook. First, we counted all rows in the excel file for each interview. We then created an excel document with columns for interview no., number of rows in each interview, and a 10% sample consisting of randomly picked rows for each sample. The reliability samples were randomized in March 2018, by a statistician using a random number generator to produce a sequence for each interview. E.g., interview number one will have rows 1-30. In sample 1. we would insert the first three randomly generated rows (e.g., 6, 17, 22), in the column for the second 10% sample we would insert the next three randomly generated rows. This was repeated for each interview. See table 2. for an example of the first three interviews.

Interview no.	Number of rows	10% sample 1	10% sample 2
1	30	3 rows: (6, 17, 22)	3 rows (insert next three randomly generated rows)
2	40	4 rows: (insert the first four randomly generated rows)	4 rows (insert the next four randomly generated rows)
3	75	8 (insert first eight randomly generated rows)	8 (insert next eight randomly generated rows)

Table 2. Example of organization of randomized reliability samples in excel.

Once we had randomized 10% of the rows for reliability-testing, we organized the scoring in excel, see figure 6. The intraclass correlation was excellent for COPIN; 0.761 and good for PROPIN; 0.723.

Interview no.	ROW	MAGNE COPIN	MAGNE PROPIN	PÅL COPIN	PÅL PROPIN	JENNY COPIN	JENNY PROPIN
1	8						
	11						
	17						
	45						
	53						
	62						
	67						
SUM							
2	10						
	20						
	23						
SUM							
4	7						
	9						
	18						
	28						
SUM							
6	6						
	25						
	27						
	34						
	37						
	43						
SUM							
7	8						
	27						
	37						
	40						
SUM							

Figure 6. Organization of scoring intraclass correlation in excel.

5.9. Methodology used in paper II only

The main outcome of this project was to find out in an RCT whether the patients who were informed by trained physicians remembered more than those who were informed by untrained physicians. The main result was a patient outcome, while the intervention was aimed at the physicians. Of course, it was also very interesting to find out how the physicians used the skills we attempted to teach them, and whether they changed their behaviour after the training. We realized that to measure how these skills were used was not straightforward, we would need to describe them carefully, and develop methods for measuring them. JG was blind to pre-or post-intervention.

5.9.1. Description of three specific communication skills

In paper II we examine how three of the skills taught in the course are utilized by these physicians, and if they use these skills more after than before taking the course. (The fourth skill was prioritizing, in which the physicians were taught to limit the amount of information. The number of information units delivered was measured in paper III). The skills are

- Mapping preferences

The strategy of eliciting the patient's current understanding, preferences, current ideas and pre-existing medical knowledge of their disease and treatment, with the intention of utilizing the response to tailor the level of their own information giving.

- Information portioning

Physicians were encouraged to portion information when presenting it to patients. "Portioning" refers to stating information in short, understandable instalments followed by a brief silence, which offers the patient an opportunity to respond.

- Checking for understanding

The strategy of checking whether the patient has received and understood the imparted information by encouraging the patient to actively explain or summarize information the physician considers important.

5.9.2. Development of methods for defining and operationalizing the skills

5.9.2.1. Mapping preferences

We explored how the physicians elicited the patient's preferences, background and current ideas regarding understanding and knowledge of their disease and treatment[188, 197]. We went through all transcripts identifying places in which the physician used the mapping patient needs and preferences strategy. I marked the utterances, and JG checked in the corresponding video sequences whether the patient responded to the question by providing any information about their needs, values and preferences. If the patient responded otherwise, JG checked whether the physician followed up appropriately, with both questions contributing to the score. This analytical procedure added extra validity of decisions. We developed a set of inclusion and exclusion criteria to clearly define the strategy through consensus discussions not only between us, but also with a video analysis group of researchers interested in medical communication. The researchers finally discussed whether the accumulated mapping questions met all criteria from the definitions. These definitions can be found in the Appendix part A.

5.9.2.2. Information portioning

We wanted to look at how many pauses the physicians made during information giving, with and without eye contact. This would allow us to see how they portioned information into instalments, and by gaze invites the patient to provide acknowledgments or signal lack of understanding along the way[153, 155, 157, 160, 223]. To analyze this turned out to be a very time- consuming task, involving microanalysis of face-to-face dialogue [224]. We used the video and audio annotation tool ELAN [225, 226].

Thin-slice methodology

To be able to get through this material we decided to use slice-methodology, which means doing analysis on a small excerpt from a longer behavioural stream[227]. Roter et al. showed that a one-minute slice of medical interaction is consistently, and moderately strongly, correlated with the entire session[228]. Similar methodology was suggested by Street a decade earlier as a means to improving the efficiency of coding discourse[99]. We analyzed one-minute of interaction from each consultation, in which the physician was giving information about one of the three MS-treatments. There is an extensive description of how we did this, and how we also chose to perform extra analyses to confirm that the pattern was indeed consistent with other parts of the session, in the Appendix part A.

Portioning pauses – instalments – eye contact

To analyze *information portioning*, we focused on the short silences that mark the end of instalments (i.e., "portions") of information. For a period of silence to be a *pause,* it had to be greater than or equal to 0.3 seconds. We further distinguished between two types of pauses. A *portioning pause* followed an instalment when the physician

(1) conveyed information that was understandable given the preceding context and
(2) looked at the patient.

In contrast, *non-portioning pauses* interrupted instalments, occurring when the physician paused

(1) before the speech was understandable given the preceding context or
(2) looked away from the patient.

The physicians accomplished information portioning every time they contributed information in an instalment followed by a portioning pause.

Our intervention tried to teach physicians the importance of pausing after delivering a piece of information. To tell someone to pause for a specific number of milliseconds (ms) is not practical. The physicians were just told to make a pause long enough to invite any kind of verbal or non-verbal response. To be able to catch most of the pauses and still be well inside the threshold, we defined 300 ms as the minimum length for a pause in our analysis. We did this on the basis of previous research in the field of conversational analysis that have defined the threshold for detection of between-speaker silences in conversations to be close to 200 ms [Ref: Walker and Trimboli 1982]. Heldner and Edlund showed that 70-82% of all between-speaker intervals were shorter that 500 ms and up to 95% were shorter than 1000 ms [ref. Heldner et al. 2010].

In the example below, in line 1, the first pause is portioning, because it follows an understandable instalment and (observable on the video) the physician was looking at the patient. The next pause in line 1 and all three pauses in line 2 are non-portioning, because the information is not yet understandable (i.e., by the end of line 2, the physician has not revealed what thyroxine "is not". In line 3, the information is understandable (the thyroxine is not a "very serious thing to get, you get dependent on that pill"). During the final pause in the excerpt, the physician glanced at the patient, thereby fulfilling the criteria for a portioning pause.

Example [P35-Dr4] 7:03.27-7:15.23 (PORT=portioning)

1. D: (og) det må man nesten regne med, /**PORT**/ men det vil jo /**NON-PORT**/
1. (and) you almost have to be prepared for that, / **PORT** / but it will /**NON-PORT**/
2. tyroksin er jo ikke noen /**NON-PORT** /altså /**NON-PORT**/ det er ikke det er ikke noe veldig /**NON-PORT**/
2. you know, thyroxine is not /**NON-PORT**/ a /**NON-PORT**/ it's not it's not any very /**NON-PORT**/
3. veldig alvorlig å få det, man blir avhengig av den tabletten? / **PORT** /
3. very serious thing to get, you become dependent on that pill? / **PORT** /

5.9.2.3. Checking for understanding

JN went through all transcripts and found all statements in which the physician performed any kind of request for the patient to verbalize imparted information back[184]. JN and JG would together develop criteria that clearly defined whether a statement fulfilled the intention of the strategy. These criteria were discussed with a video analysis group of researchers interested in medical communication. The decision on whether a statement met the definitions were conducted by consensus coding. JG checked in the corresponding video sequences whether the patient responded to the question by actively explaining or summarizing given information, or by asking questions.

6. Summary of results

I will present the papers in the order of how we analysed the data; beginning with paper I, then paper III, and finally paper II.

Paper I

The result of the work accounted for in paper I is a 2-step complex information transfer measurement system consisting of "Counting Complex Orally Provided INformation" (Count-COPIN) and "Counting Patient Recall of Orally Provided INformation" (Count-PROPIN). It is a method for defining and counting complex oral medical treatment information provided in unscripted conversation, designed to compare how much information the physician provided to how much the patient recalled. It is a two-step method: First the coder uses Count-COPIN to analyse the information provided by the doctor. Then the coder moves on to Count-PROPIN to compare patient recalled UoI's to the UoI's counted with Count-COPIN. The system can be modified to counting information about other data than information about medical treatment.

Coders achieved good inter-rater reliability, with intra-class correlation for patient recall: 0.723, and for doctors: 0.761. The complete measurement system is shown in the Appendix, part B.

Paper III

We used Count-COPIN and Count-PROPIN to measure patient recall of complex unscripted medical treatment information in the RCT accounted for in paper III. The primary outcome measure in the RCT was patient recall rate, while the secondary outcome measures were the number of UoI's provided by the physicians, and the effects on patient involvement through questionnaires.

- Patient recall rate was 0.37 (SD=0.10) pre-intervention and 0.39 (SD=0.10) post-intervention. The effect of the intervention on recall rate predicted with a general linear model (GLM) covariate was not significant (coefficient parameter 0.07 (SE 0.04, 95% confidence interval (CI) [-0.01; 0.15]), p=0.099). We could not show that the customized communication training for the physicians improved patient recall rate.

- The physicians tended to provide significantly fewer information units after the training, with an average of 91.0 (SD=30.3) pre-intervention and 76.5(SD=17.4) post-intervention; coefficient parameter -0.09 (SE 0.02, 95% CI [-0.13; -0.05]), p<0.001. There was a significant

negative association between the amount of provided information and the recall rate (coefficient parameter -0.29 (SE 0.05, 95% CI [-0.39; -0.18]), p<0.001).

- We found no significant effects on patient involvement using the Control Preference Scale (CPS), Collaborate, or Four Habits Patient Questionnaire (4HPQ).

Paper II

When we could not show that customized communication training for the physicians improved the patient outcome of recall rate, we were curious to investigate through a qualitative exploratory study whether the physicians changed their behaviour after having been through training. The RCT was not powered for detection of such changes, however, observations in this study could still serve a hypothesis generating function, leading to later studies. We discovered that there were no existing methods for describing the exact strategies we wanted to investigate, so we developed methods to describe, and thus be able to measure them. These methods are the result in paper II.

Data were 34 video-recorded simulated (but unscripted) interactions concerning information about medical treatment options, between 17 physicians and 34 multiple sclerosis patients, collected in the RCT accounted for in paper III, before and after a brief course on information sharing. We used microanalysis of face-to-face dialogue as an inductive video analysis method to operationalize physicians' use of three information-provision strategies. We operationalized (1) *mapping the patient's preferences* and (2) *checking the patient's understanding,* and pauses indicative of (3) *portioning information*. We used the results to explore Kirkpatrick level 3 outcomes from the same RCT as examples. Patients responded to portioning pauses as expected: whereas 91% of these pauses elicited an immediate patient response, only 23% of non-portioning pauses did so. We could not show significant physician behavioural change regarding our three strategies. The RCT was, as stated above, not designed for this outcome. The main results are detailed analytical definitions, criteria, and assessable, quantifiable outcomes for each of the three strategies.

Data

Data were collected in Akershus, Norway during the fall 2016. 17 physicians employed at the neurological department at Akershus University Hospital (AHUS) participated; 7 were female, mean age of 41, median age 39 (range 29-57 years old), and had between 2 and 29 years of work experience (median= 11, mean=13). Five physicians declared not to have had any kind of communication training before. Eleven had received some such training during medical school, three

had received additional training after graduating. One physician declared only to have received some training after graduating.

Patients with relapsing-remitting MS, currently on none or any of what was at the time described as first line drugs, not previously exposed to the decision to begin with a second-line drug, were identified in the electronic patient records at Ahus and invited to participate through mail and telephone. We achieved 34 participating Norwegian-speaking patients with MS between 29-66 years old, median age 48, mean age 46, 25 were female.

The physicians each informed 17 patients on second-line/escalation therapy options, then participated in a three- hour long training intervention focusing on how to improve communication in exactly this situation, before meeting with a new patient each. Each consultation was followed by an immediate recall interview, and patient questionnaires. The recall interviewer watched all consultations on-screen simultaneously in an adjacent room and used a specially developed check-list to keep control of the information given, and to be able to give cues that would jog the memory.

All 34 consultations and interviews were videotaped and transcribed verbatim. 1652 statements containing information about our predefined three treatment alternatives were identified.

7. Discussion

In the first section I will discuss methodological considerations, in the second, I will discuss the results of the papers in the context of existing literature. All papers are based on data from one RCT. We have used the material from the RCT to develop assessment tools for measuring information transfer and recall, as well as physician behaviour change.

7.1. Methodological considerations

7.1.1. Reflexivity

When measuring qualitative data, as videotapes and transcripts are, it is unavoidable that the work is coloured by the researchers' knowledge, their language and their communication skills. As a researcher, it is important to be aware of this, and to reflect on one's biases.

The role of the team

Through the iterative process with the code book in paper I, my co-researchers' and I built our own road through team work, reflection and discussion leading to consensus. After concluding with the need for developing entirely new methodology for counting information, we began at absolute scratch. At the start of the process, all members brought creative ideas on how to proceed to the table, which started a creative discussion. Each member brought individual relevant expertise to the table; MN had experience of more than thirty years of working with medical information. PG had been studying clinical communication for more than fifteen years. My background as a specialist in neurology was an advantage because of the familiarity with MS, its treatment, and the situation we were studying. Within each meeting, we managed to come to conclusions that we could agree on as stepping stones for the next problem to solve. Our personal judgement was involved in all decisions. Disagreements were resolved through group discussion leading to consensus. Although each of us might have our own biases and emphasise different details when analysing the material, the repeated discussions and our different perspectives should mitigate the risk of undue biases.
During the coding work done in paper III, the coders were the same as the developers of the measurement system. This was an advantage in that all coders were very familiar with the methodology, and we did not need to train other coders.
When working on paper II, my background made it possible for me to explain medical content and translate Norwegian expressions from the videos and the transcriptions to my co-researcher JG. JG had expertise of microanalysis of face-to-face dialogue, interactional coordination and conversation

analysis. Disagreements were resolved through discussion leading to consensus, and just as described for paper I, this should mitigate the risk for undue biases.

Personal reflexivity

During the time I worked with this study, I often had conflicting feelings. The medical communication field was new to me, and less dominated by physicians than I was used to in my previous contact with research. I was introduced to research on medical communication and SDM, and found that there was a lot of evidence showing that physicians did not do a very good job when informing their patients. When going to health care communication conferences, I found my own profession a minority in the field, and the criticism towards it overwhelming. At the same time as I tried to find my new role as a medical communication researcher, I knew so well from experience how extremely difficult it can be to communicate with different patients. Even though I usually enjoy and find communication with patients one of the positive parts of my everyday work, I also know intimately how a professional consultation can completely deteriorate due to factors one is not prepared for, like a patient's fear or anxiety, distrusting family members, language issues, cultural differences, cognitive problems, or just incompatibility of personalities. The demands that law-givers and health-care researchers made on my colleagues and myself sometimes seemed inhumane. Not only are physicians often limited by lack of time and space beyond their control, they are also people, with different talent for reading others, for verbalizing, for interpersonal connection. I often felt the need to say: "We physicians are also human beings; you cannot expect us to be perfect." In my meeting with this research community, I felt defensive on part of physicians in the beginning, but realized there were potentials for improvement. I cannot rule out that these experiences may have affected assessments and interpretations on my part.

Questioning a specific decision

Initially, the planners of this study wanted it to additionally yield a consensus-based information priority list designating which information should be given priority as crucial and which could be considered optional in consultations about treatment choices regarding MS treatment escalation from what was previously seen as first-line treatment. According to a study of the information preferences of patients with MS, patients found information about symptom alleviation, diagnostic procedures and prognosis most relevant[73]. It has been reported by patient participants in a study by Manzano et al. that neurologists tended to provide a narrow set of treatment options on the basis of three criteria: Clinical incompatibility, treatment approach and funding, and their own clinical judgement/preference[229]. Joyce et al. found that there were marked differences between

physicians in the kind of information they imparted[113], but we cannot know if this was due to tailoring or to varying opinions between physicians about what is of importance. I am not aware of any study on professional consensus on which information neurologists consider more important, but the need for clear, concise and balanced information has been demanded by several[32, 230]. In 2016, we discussed how to proceed with this in a meeting between a professor of medical ethics, an MS patient representative, my PhD supervisor and myself. It was then decided that a list of crucial information would be impossible because patients had such different needs. In retrospect I regret not questioning this decision more vigorously. Such a priority list could have been a useful tool for neurologists in their everyday work: the advantage being that they could make sure not to forget information deemed highly important. Possible disadvantages could be less tailored information, or that physicians constantly pressed for time might choose to interpret the "must inform about" on the list as an excuse to not go deeper. Personally, I think it would have been a very interesting study to use the measurement system in paper I to compare patient recall of the information given that was deemed more important by consensus compared to the information deemed less important.

7.1.2. Validity

Selection bias - are the patients in the intervention group and the control group in this study similar to one another and to the larger population from which they are drawn[231]?

Akershus University Hospital has a catchment area of around 600 000, accounting for about 10% of the Norwegian population. Our included patients were found in a record of Multiple Sclerosis patients diagnosed at the neurological department of Ahus between 2009 and 2012. All patients within that time-span who met the criteria were attempted contacted. This approach should not entail any selection bias. One could, however, argue that the fifty-three patients who agreed to participate could somehow be different from the eleven who declined. It is not entirely unlikely that their reasons to decline also would be relevant for their recall ability. Most who declined gave reasons that they were too busy or were afraid it would interfere with work, which they prioritized highly, already having a somewhat reduced function. Some did not give reasons for declining.

We did not check for previous knowledge among the patients. McCarthy et al. in 2012 found that those with lower health literacy had poorer ability to recall information[115]. It has also been showed that those with a lower health literacy profit more from having their information structured[57]. If we had tested the health literacy of all participating patients [232], we could have controlled for this confounder.

We do not have data on cognitive impairment, which could have been of interest in this patient group[169]. Even in an early stage of the disease, cognitive problems could be present and measurable by cognitive performance tests[233]. Measurement of whole brain atrophy could also have been interesting[234]. There is no strong evidence for a relation of memory performance and whole brain atrophy, however, a tendency towards correlation with ventricular size[235] and also thalamic and hippocampal atrophy[236, 237]has been shown. I did want a neuropsychological assessment of the patients beforehand, but this was unavailable in our time frame. It is possible that patients who felt that they suffered cognitive impairment more often turned down participation in the study than patients who did not. However, most who declined gave reasons implying that it was their high activity that interfered with their participation. My conclusion is that that the patients were non-selected regarding eventual cognitive affection and health literacy is realistic and representative for a recently diagnosed general RR-MS population.

There were more female than male patients among the included, see Table 3, which reflects the fact that there are more MS among women[6].

PATIENTS	CONTROL GROUP			INTERVENTION GROUP			TOTAL		
		F	M		F	M		F	M
	n=17	(n=13)	(n=4)	n=17	(n=14)	(n=5)	n=34		
Median age	48	50	31	48	49	45	48	49	45
Mean age	47	49	35	45.4	48	45	46.9	48.2	40.6

Table 3. Patient age.

There is research suggesting that women perform to a higher standard than men when it comes to recall [238]. The genders divided themselves evenly by randomization with five males in the control-group and four males in the intervention-group. Age was also quite evenly divided, with the exception of the males in the control group being younger than the rest, see Table 3. None of the groups had an old enough population to be defined as older adults, which are >60 in most studies about age and recall[239, 240].

In principle, the randomization process should counter any effects related to health literacy, brain atrophy and neuropsychological functioning between the pre- and post-intervention groups, but lack of such data prevents us from exploring this possible reason for lack of effect. Having as low an *n* as

we do in this study, we cannot ignore the fact that such random differences may have had importance.

Loss of subjects through the course of the experiment

Dropout or withdrawals threatens the validity of results, as those who withdraw may differ from those who complete a trial. Differential dropout (attrition) may also bias results[241].
Physicians withdrawing could have raised the question of bias; it is not unlikely that physicians who disliked the training, or did not wish to change their behaviour, would drop out at a greater rate than those who were positively inclined. However, as the physicians were their own controls, both pre- and post-intervention results would have had to be removed. None of the physicians withdrew from the study.
We included 42 patients for randomizing, when only intending to study 34. Thus, we had 21 patients in each arm, that is four substitute patients in each arm in reserve, to be contacted if a patient could not participate at the allotted time, no longer met the inclusion criteria or wanted to quit the study. Three patients, one from the control arm and two from the intervention arm, quit after the study had begun, but before it was their turn to partake. They were all replaced by substitutes already randomised to the respective arm. This should not have made the groups less representative of the population.

Hawthorne effect: when people behave differently because they know that they are being watched.

How did it influence the physicians and the patients that they were being video-recorded? We cannot exclude a possible Hawthorne effect; a well-known form of reactivity in which subjects modify an aspect of their behaviour in response to their knowing that they are being studied[242]. Physicians do like to be seen as competent. It is therefore likely that being observed made them keen to do well, that is, to adhere to the taught strategies. They were not taught the strategies before their first attempt, which means that it is unlikely that they consciously would have tried to use them then. The observation may have made the physicians more nervous.
Our study does not allow for an estimate of the Hawthorne effect. How being observed would affect the physician differently between the first and second consultation, either because of familiarity with the setting or the in-between teaching session, we cannot know. That any effect would be large enough to neutralize a real effect is highly unlikely given the small observed pre-post difference and 17 involved physicians.
We must consider that the fictive situation may have affected how much the patients remembered. Some of the patients were concerned and apologetic about not remembering enough, voicing during

the interview that they worried that this would reflect badly on the physician they had consulted with.

The conditions were the same for both the intervention and the control groups in this matter.

Treatment fidelity - reflects the extent to which an intervention is accurately implemented

Looking at the training intervention for the physicians, the following questions are relevant:

1) Was the intervention implemented correctly?
2) Was the intervention implemented consistently for all physicians?
3) Was the implemented intervention of good quality?
4) Was the implemented intervention long enough?

The training was done in three 3-hour long group sessions with 4-7 physicians in each group, all held by the same experienced professor with extensive experience in teaching communication to medical students[243].

The three sessions would not have been absolutely similar, as they involved roleplay, which means that the content will be partly built between the participants. Interactivity, roleplaying and rehearsing particular settings has previously been shown to be important factors in developing competence[199, 200].

To have one large session for all physicians together would imply less time to try the strategies in role-play for each physician, and thus a reduction of quality. If we were to be sure that the intervention was consistently enough implemented for all physicians, we would have had to analyse changes separately for the three groups, something we did not do.

The three training intervention sessions were all held within seven days. To effectuate a consultation the physician needed to have space in his or her schedule at a time that worked out for the patient and the researcher. The pre-intervention consultations were held over a time frame of 37 days. The post-consultations were held over a time frame of 71 days, mainly because one consultation was cancelled due to disease, and it was difficult to find a new date acceptable to all parties. (The other seventeen post-intervention consultation were held within 31 days). The time interval between the two consultations, and also the time interval from the intervention to the second consultation, varied from physician to physician. as shown in *Table 3, Time between training and second consultation*. The shortest time between intervention and second consultation was two weeks, the longest was twelve weeks, with a median of four weeks. This time difference may have led to an inconsistency in how much of the training that was retained when meeting the second patient.

It is not possible to reliably answer whether the duration of the training was long enough. Two independent studies have shown that a 5-hour communication skills training for residents significantly improved specific elements of end-of-life conversations[201, 244]. Tarn et al. found that a 1-hour training for physicians improved the content of and enhanced patient ratings of physician communication about new medication prescriptions[204]. Others have also been able to show significant effects of individualized shorter communication training interventions[202]. Previous research advocates longer courses, due to a potentially moderating effect on efficacy of training duration[207], but there is no consensus on the perfect duration. In 2017, Kasper et al. showed that an intensive training module that would demand only 2 hours and 15 minutes of the physicians, improved their SDM skills, however, they could not show any improvement in the patients' SDM behaviour[203]. Optimal duration is very hard to evaluate due to the heterogeneity of the interventions. On the basis of this we came to the conclusion that a short course could be efficient if it was tailor-made and situation-specific when making our decisions.
The pedagogic quality and the length of the intervention is also discussed further down in 7.2.

Measurement bias

We did not encounter elements of dialogue that we could not comprehend. We approached the data without being tied up in earlier frameworks or coding systems. The challenge was to agree how to define what we were measuring. That we achieved a good interrater reliability, allows us to assume that the numbers we present concerning units of information are valid. Random measurement errors between observers do not cause bias.

Measurement bias cannot be completely ruled out, but I consider it to be a minor problem not likely to have altered the conclusions.

External validity

The question here is whether one could expect the same results of the intervention if applied to other settings in medicine where complex, unscripted information is provided to patients with exacerbation of a chronic disease.
We cannot know if the lack of change could be attributed to the teacher in the courses, despite his 15 years of experience in teaching clinical communication to physicians, or that this particular course was shorter than the ones he usually runs. There is evidence that even shorter courses have had effect; Tarn et al. had a 1-hour intervention that improved both the content of the interactions (objective physician behaviour) and the patient ratings of physician communication[204]. However, the training was combined with a patient information handout, which may have made the patients

more aware of the physicians' communication behaviour. Werner et al. did a 30-minute intervention for advanced medical students that improved information recall of medical laypersons in simulated informed consent talks[117], This study was less complex than ours, however, with a standardized set of 20 information items. The point of giving these examples is the heterogeneity of behavioural studies; it is very hard to draw conclusions from one that will be valid for another. Teaching interventions will always be dependent on the people involved, in that sense a direct transferral of conclusions to other, even similar, situations, cannot be inferred.

External validity is also about transfer from experimental observations to real life. In this study, both physician and patient participants reported the situation to feel realistic, and we received feedback from the patients indicating emotional and motivational realism during the sessions.

7.1.3. Discussion of particular design choices

The fictive part of the intervention design

The design of the study had two main innovations: (1) inviting real patients with Multiple Sclerosis who had not yet been exposed to the situation of possible initiation of second line MS treatment, and (2) putting them in a fictive scenario of having experienced recent relapses and coming to discuss a medication change. Similar techniques have been used before. There is previous evidence that recall of fictitious medical information by volunteers closely parallels recall of true medical information by patients[128]. In McCarthy et al.'s study, participants were asked to imagine having a particular condition or symptom and that they were receiving live information about it. They were then shown a two-minute information video of a physician counselling them about the condition, before recall was tested. The participants did not have any related condition to the one they were asked to imagine having[115]. We included real MS patients, receiving individually tailored and unscripted information about their own condition – but pertaining to a made up, possible future situation that we believed they easily could relate to. These choices were designed to achieve as much ecological validity as possible within the fictive scenario. Specifically, the design enhanced relevance and participant motivation, as the patients in the study were as similar as possible in disease burden, cognition, knowledge and motivation as possible to true patients in that same situation[125, 174, 175]. However, the choice to combine a made up, but possible future situation with real patients meeting real physicians who gave them real and unscripted information was a deviation from mainstream RCT's.

Our feedback from the interviews indicated these choices were successful. Participating patients reported being interested in the information and finding the setting relevant to them. Such

motivated interest and relevance, suggests that their recall of information physicians provided was an accurate representation. If we had managed to do the same study in real life, without the fictive scenario, we might have seen higher patient motivation for receiving information, but such a choice could also have involved more anxiety[125], which possibly could have influenced effects in the RCT. Some patients described, in line with previous research[175], that it was tough to receive even fictive information about disease progression, and some described the information as overwhelming, heavy and/or frightening. This may have contributed to less recall, as previously shown[195]. Previous research on the connection between anxiety and recall is however heterogenous. In Dunn et al.'s study, patients with high anxiety did not recall less information than those with low anxiety[119]. On the other hand, Anderson showed that the more anxious, the more the patients in his study remembered[114]. There is some evidence from animal studies suggesting increasing memory with stress to a point where performance decreases as the stress levels intensify[196]. Ley and Spelman showed that recall was lower when anxiety was very high, but also when it was very low[111, 126]. The association between emotional stress and patient recall of medical information is not straight-forward, and to simply reduce emotional stress may not be enough to increase information recall[127]. Some individuals have better stress coping strategies than others. A nervous person may experience more stress than a calmer. The stress levels thus may have affected recall, but this would have been on a very individual basis. The setting was realistic and similar to how this would have been with MS patients who really was in this situation.

Using the "fictive scenario, but real patients" design choice was a necessity to be able to conduct the study. Spreading data collection over a long time- interval by only recruiting in real clinical situations would introduce higher variability in many aspects, including the actual clinical situation, the distribution of time between observations and teaching sessions, and a higher risk of drop-out both on the patient and physician side. So, regardless of the negative result of the intervention, we think there are good reasons for repeating the design of the study, if not the specific intervention.

The physicians acting as their own controls in the intervention design

Another design choice was the physicians first meeting one patient untrained (in this context), then receiving training, and then meeting another patient. This may have led to the physicians being more at ease at their second consultation, being more used to the situation. There were however quite large variations in how much time that passed both between training and second consultation and between first and second consultations for each physician, see *Table 4.*

Since their achievement were not compared to each other, but to their own pre-intervention achievement, I consider this of little importance for the validity of the RCT results.

	Time between first and second consultation:		Time between training and second consultation:	
Physician ID:	Days	Weeks	Days	Weeks
4	71	10	28	4
3	54	8	20	3
21	45	6	12	2
24	63	9	24	3
5	65	9	30	4
20	54	8	26	4
2	63	9	29	4
23	52	7	26	4
18	42	6	22	3
12	62	9	37	5
25	37	5	19	3
17	38	5	16	2
13	98	14	83	12
19	49	7	32	5
26	23	3	19	3
6	37	5	29	4
11	29	4	27	4
Minimum:	23	3	12	2
Maximum:	98	14	83	12
Mean:	51.9	7.3	28.2	4.1
Median:	52	7	26	4

Table 4. Time intervals between consultations and between the intervention and the second consultation.

That the physicians changed their status from untrained to trained has been done in previous studies[172]. It enabled us to evaluate immediate outcome[143] and compare their achievement before and after training, as we described methods for in paper II. An advantage here is that variance tend to be lower within than between subjects which gives more precise estimates. If we had looked at two separate groups of physicians, we would not have been able to make this comparison.

We cannot rule out subtle effects, like that the possibility of an effect of doing the same assignment twice. Since the intervention had no significant effect on recall rate, we do not consider this a problem for the reliability of the results.

The recall interview

All interviews were performed by me, a choice made to avoid differences in approach and quality. There were marked differences between interviewers in the amount they elicited in Joyce et al.'s study[113], and this was later shown to be a problem also in PICcode[120]. The funnel-shaped structure we used for each topic, starting with very open questions, then specifying, is recommended by Rachlew et al[92], to obtain high levels of detail. By asking for progressively more specific information in sequence, based on the previous answer, you can get increasingly detailed answers[179, 180]. We found this method useful for structuring the interview.

Bertakis also let the interviewer be in the room during the consultations in order to be able to give open-ended interview questions, however, in her study the physicians gave averagely less than 14 items of information, while we had an average of more than 76 items[184]. Observing the previous consultation in real-time on-screen and taking notes with my self-developed Check List ensured that I could adapt every interview to the unscripted content of each patient's individual consultations, and thus give high quality cues [182, 183]. Our experiences fit well with other studies that has shown that the brain needs retrieval cues[178] and structure[57] to recall information in a given setting, see 3.2.4.2. In the real world, we do not remember everything at all times; we mobilize our memory when cued[96]. A fixed interview would not have covered the individually tailored information delivered by the physicians as well, as also seen in a comparable concurrent study[120]. The Check List made me able to reliably cover each topic the physician had mentioned with open questions functioning as retrieval cues for the patient. Thus, I tried to emulate the way memory works. Based on previous research and our experiences, I find it likely that we managed to extract an amount of recalled information similar to a lifelike setting of memory mobilization[96, 178-183].

Thin-slice methodology

To investigate the use of pauses in paper II, we chose the use of thin-slice methodology. This technique raises questions about the validity; how well does the thin slices really correlate with the totality of the recorded behaviour? An alternative would have been to analyse the entire material. However, since the analysis of pauses was very time-consuming work done on videotaped material, this would not have been possible within our time frame. While previous research had shown that analysing a thin-slice of material yielded results that matched a larger sample [228], we decided to do two extra analyses to confirm that the pattern in our thin slices was consistent with other parts of

the videotaped consultations. First, we analysed one additional minute of information delivery from both consultations of three physicians (i.e., six interviews). Second, we analysed the consistency between two slices from different parts of the consultation (time vs. topic). These two checks indicated that the initial slices we had extracted were indeed representative of the whole encounter. Our extra analyses resonated well with previous findings[228].

Portioning

Among the instructions given to the physicians during the intervention were to use clear language and fewer words[111, 114]. They were also instructed to pause after delivering a chunk of information paired with a visual check-in. This was to see if the patient follows, or need clarification, which has been previously shown to be beneficial for recall[161-163] and comprehension[155]. Because it is not meaningful to tell someone to pause for 0,3 second, the physicians were told to pause for “a second or two”. Conversations are full of silences of various durations, but when analysing for such portioning, we found very few pauses as long as a second or two. We had to decide which duration of silence should constitute a perceptible and practical limit for a pause between instalments. We chose 300 ms as the minimal duration for a pause, because it was the least duration that both analysts found practically easy to spot and perceive as a pause. We found also that this duration fit with definitions in previous work[245, 246]. Heldner et al. confirmed that the vast majority of pauses in conversations are shorter than 500 ms[246].

7.2. Discussion of results

Count-COPIN and Count-PROPIN

In paper I we have developed a measurement system for counting complex orally provided information, Count-COPIN, and for counting the patient recall rate of the information provided, Count-PROPIN. It was designed for assessing recall in MS patients who receive complex, unscripted information about treatment escalation, but can be adapted for counting other phenomena as well.

Why did we not use an existing coding system? There are several coding systems that describe patient-physician interaction[99, 101-103, 186, 247, 248] or categorize content of conversations thematically[98, 100, 119]. Dunn et al.'s taxonomy was not about medical treatment, and thus their categories did not meet our needs[119]. The coding framework by Tarn was developed to describe communication about new prescriptions, which probably could have been modified into describing information about our treatment options. The codes represent conversational content, and organizes them thematically, e.g.: Frequency of medication intake; classification split between vaguely, explicitly or implicitly. RIAS classifies and categorizes an utterance after its function, and after the communication behaviour used[248]. It can provide the number of different types of utterances, but lacks strict definitions of the coding categories[97, 249], and we cannot use it to show which specific information unit a patient remembers. The systems [97, 100] did not have the capacity to encompass unscripted, unlimited information and its recall in a way that takes into account paraphrasing, gist understanding, listings and other phenomena present in natural dialogue. Rather than trying to modify an existing system that was developed to measure other phenomena, we found it more propitious to tailor a methodology directly to what we wanted to do.

1. Size of one unit of information (UoI)

We defined a UoI as the smallest meaning-bearing unit containing medical treatment information possible to identify. The idea resonates with how others have defined it before us[97, 119]. To be countable it needed to have a contextual anchor. Simultaneously to our work, Lipson-Smith et al. developed a related type of codework named PICcode intended to measure recall in consultations needing an interpreter. They also defined a UoI as a segment of speech expressing a single idea concerning medical issues[120]. When we started to look at the unscripted information data, we saw that a sentence or an utterance could contain multiple and different units of information, belonging to different categories. Other taxonomies, for example Dunn et al's [119], put different information items in categories. Tarn et al. categorized the information thematically [100], which would not have

enabled us to reliably score the exact recall as a percentage, only to claim that the patient remembered information from said category. We wanted to extract all information units from free speech phenomena with paraphrasing, incomplete sentences, 'gist' understanding, etc. An example would be that if the physician lists five side effects, our system has a way of scoring the generalization that there were multiple side effects, as well as individual items. Categorical and descriptive taxonomies would not allow us to catch all countable information.

2. Organization of the units of information

Every unscripted consultation between physician and patient develops in its own way, not two conversations are alike, and the communication is built between the two. Most of us will make pauses, sometimes cut off a sentence midway, or let it trail away into dissolution. Sometimes we digress, then take up the tread again, non-verbally checking that the other is still following. Physicians are no different. If the information units were standing on their own, the coder would not know what e.g., "that last drug you mentioned" meant without having to read through the whole transcript and perhaps even watch the video-recording. Even a single word, like "lethal", could be an information unit. But to be countable in this work, it had to be meaningful; it had to be possible to connect it to a treatment, or as in the case of "lethal", an answer to the cue on whether the patient remembered anything about side-effects of an aforementioned treatment. To be meaningful information each unit needed to have a contextual anchor. This necessitated that I organized the material in sentences containing information under the different treatments before presenting them to the coders, which made the task of coding 1652 statements about our predefined three drug alternatives possible. One problem this led to was that the analysis became very time-consuming, see limitations.

3. Understanding. When is a reproduction "good enough"?

One major challenge was whether a given UoI was correctly interpreted in the patient's reproduction. One way to make sure that the information had been transferred was that we demanded that the UoI should be contextually anchored also in the data produced by the patient. We know from previous studies that patient understanding is often incomplete [32, 53, 250]. There are situations where you cannot be absolutely certain that the patient has fully understood all aspects of the information even if she remembers and reproduces it. How could we be sure that our judgement on whether the patient reproduce a UoI well enough is appropriate? Initially, we had an idea of gathering those pairs of UoI's from the physician and the patient respectively, in which this was unclear, and send them out to patients with MS in a survey to have them decide on a scale 0-5

whether the information is well enough reproduced in the patient's answer. But situations that would fit in such a survey were not as numerous as we had envisioned, and the survey procedure would have needed extensive planning and time we did not have[251]. Instead, we chose to accept "gist" understanding, that is; intention, not ability to reproduce exact wording, and to always let a situation of doubt end up in favor of the patient recall score. The choices described above reduced personal judgement when coding, and thus had a positive effect on the inter-rater reliability.

4. Content quality

When counting recall, the aspect of content quality lost its importance. This study was not about discovering which parts of what the physician said that were scientifically correct, it was about remembering what the physician said. We therefore disregarded whether the medical information was correct or not when defining what to count, both in Count-COPIN and in Count-PROPIN. This does not in any way imply that we do not find the quality of the information important. In the situation of receiving information about MS escalation treatment, the quality of the information *is* important. It could be interesting in a further study to see how many incorrect UoI's that are given in a specific informative setting. Count-COPIN could be of use to count these.

When studying the post-consultations interviews, I noted that some patients spontaneously declared that they had found one of the treatment options irrelevant while the physician described it, and therefore had stopped paying attention to the details about it.

> Example: "den blokket jeg ut fra hjernen min, for den virket ikke interessant i det hele tatt"
>
> „I blocked that one out of my brain, because it did not seem interesting at all" [about Gilenya, JN anm.]
>
> *[Pasient X Lege Y; Position: 6|83-6|83; Author: Jenny Nordfalk; 09/11/2017 15:09]*

This observation is in line with previous findings. It has previously been shown that patients do not treat all information as equally important. Joyce et al. found that there were clear differences between patients in the kind of information they retained[113]. For example, they remember more information about their treatment than about their diagnosis[114]. A recent study found that physicians and patients often do not agree on which information is the most relevant[59]. In the example above, one interpretation is that the patient found this treatment option irrelevant for her, and therefore she did not pay attention to the information about it. Whether the patient decided upon this irrelevancy based on factual information about the treatment option, or if physician influence had something to do with it is hard to say. Studies have showed that physicians sometimes

use subtle persuasive tactics[252], perhaps even unconsciously, to influence a choice[253]. We saw during our work with paper II, that the physicians and patients sometimes co-constructed their bodily conduct and gaze so that one treatment option was rendered less favourable. This observation fits well with previous research on dialogic interaction, in which it has been proposed that mutual understanding is an interactive process that the participants in a conversation accomplish together[254, 255], and with research showing that physicians and patient collaborate towards solving the patient's problem in a consultation[256, 257]. It confirms previous theories that verbal and nonverbal means of communication are complementary tools[258]. If we had rated different information after how important the physician thought it was, we could have explored whether these information units were recalled at a higher rate. It is an interesting idea for a later study to adapt the measurement system to explore whether the information the physician values as more important is recalled more often than other information.

Discussion of findings in the RCT

There are previous studies who have examined patient recall rate of oral, pre-defined information about medical treatment, but I am not aware of any study who had done so in unscripted, unlimited dialogue except Lipson-Smith et al., who developed a methodology called PICcode, with many similarities to ours. They too dissected the information into units to be counted and compared to post-consultation recollection. The greatest difference from our study was the lack of a check-list and thus a cue-system, which, in addition to the use of multiple interviewers lead to variable quality of the semi-structured recall interview. This study was published in 2018, when our methodology development and RCT data collection was already finished[120]. Another related later study was published by Østen et al. who videotaped unscripted discharge conversations, but the assessment of recall was only rated on a 3-point scale of none – partial – complete for each topic, and thus not transferrable to our work.

In the case of a negative result (here: no effect of the intervention), the possibility of a type II error is relevant. That we could not show a significant improvement in patient recall, lead us to speculate on possible explanations.

First, did we achieve a change of physician behaviour? Yes, the one significant effect of the intervention shown in the RCT was that the physicians provided a lower average number of oral information units after training. The training was sufficient to improve physicians' ability to prioritize information. We also saw that the recall rate was reduced inversely proportional to the amount of provided information, which concur with results in previous studies[114, 128, 166, 240]. In these

aspects, our findings show that physicians did indeed change their behaviour as a result of the intervention.

The reduction of the amount of information is a physician behaviour change and thus an immediate outcome[143] at a Kirkpatrick level 3[142]. An increase in patient recall is an intermediate outcome[143] level 4[142]. Evaluation becomes more difficult at higher levels. The link between the training and the outcomes becomes more indirect as the levels increases, and more additional parameters affect the exchange of information[142].

However, they did not change their use of other strategies that were taught, as seen in paper II. Observations from this study can still serve a hypothesis generating function even though the RCT was not designed for the measurement of this outcome. The methodology on description and measurement of the three strategies that we created in this study enabled us to get a reliable effect measurement of the intervention of teaching these strategies to the immediate outcome of physician behavioural change. There is a hypothetical association between step one: to show what is actually happening when a physician changes her behaviour due to learning communication-enhancing strategies, and step two: to show that the patients recall a higher rate of the information. Unfortunately, the intervention providing the data for this study had not the significant effect we had hoped for on the physicians' use of these three strategies. If a causality exists between reductions of UoI's and the intermediate outcome of an increase in patient recall, it was not strong enough to produce any significant such, even though we saw a negative association between the amount of information and recall rate - which concur with findings in previous studies.[114, 128, 166, 240]. We cannot rule out unknown confounders in the complex social interaction that communication is; for example, a person who found portioning and limiting her information easy, could also be a naturally good communicator when it comes to other strategies.

Second, was the pedagogic quality of the intervention good enough? When transferring methods from training to clinical practice, one challenge is that the educators often lack experience in clinical practice[259]. Literature highlights the importance of trainer experience[260], and previous studies have shown that physicians are given high evaluations by their students in small-group communication skills training[261], which this intervention was. The developer of this training intervention had both personal clinical experience as a physician and extensive expertise in teaching communication to medical students and physicians[243, 262]. Our training was not purely didactic and included clinical role-play, as previous studies have shown that including interactivity or practical role-playing sessions together with didactical moments is important[123, 199, 200, 261]. The strategies were to teach the physician to map patient preferences in order to prioritize with, or tailor

their information to, patient needs[187]; to limit the amount of information[111, 114], again by prioritizing[187, 191]; to portion the information[155, 157], which we defined as pauses with eye contact, in order to catch misunderstandings or lack of understanding[163]; and to check that the patient had understood[116, 133, 135, 184, 192]. These are strategies considered to increase involvement and recall[129, 135, 184, 187, 192]. Lack of pedagogic quality can't be ruled out, but is not very likely.

Third, were the physicians sufficiently motivated to change their behaviour? We know that motivation is necessary to achieve such change[122]. Did they consider themselves in need of communication training? There are research showing that there is low concordance between how well young physicians believe their communication skills are and how observers rate them[263, 264]. The sex, age, clinical experience, and previous communication courses in the participating group of physicians were very similar to participant physicians in an earlier intervention study in the same hospital providing a 2-day course demonstrating a significant effect[172]. In both studies, participation was voluntary, and any bias related to self-selection cannot be inferred. If in the current study we had observed a significant effect, a discussion of a possible effect of higher motivation[265] could have been used as an argument towards caution against implementation elsewhere.

Fourth, was the training course sufficiently relevant? The training was tailored specifically to complex information-giving about MS treatment escalation. Most of the physicians did not work with MS-patients on a daily basis. Still, the training was not at all about learning MS-related facts, but about how to communicate unsure, complex and potentially emotionally upsetting information about treatment options. This is a situation most neurologists would recognize and therefore perceive as relevant. We do not know whether the individual physician found the training personally relevant.

Finally, perhaps the course was too short. It was indeed merely three hours long. Based on an anticipation that the public hospitals would not fund comprehensive courses, we aimed to demonstrate a high effect of a brief course. This brevity was a deliberate choice to accommodate feasibility and economic aspects[207, 266], explicitly testing whether short courses could be effective, and thus possibly implemented on a higher scale in the public health care system in Norway. Although there are some indications in the literature that brief courses *could* change physician behaviour[30, 117, 201-206, 267], most studies highlight the importance of communication training interventions to last more than one day[123, 207]. Moore et al. conclude in their review that the optimal length of training remains an unanswered question[260]. In light of this, the negative result regarding effect on recall was not very surprising. The 3-hour course may not have allowed sufficient time to discuss the reasoning and the scientific anchoring behind the strategies to convince

the physicians to use them. Observations in paper II support this. Our study adds to the body of research that advocates the importance of time and follow up when it comes to clinical communication training.

Publication bias is a challenge for intervention studies. Studies with favourable results are more likely to be reported than studies with null findings[268, 269]. Negative findings might provide indications for what may have effect and what may not when delivering complex interventions aimed at improving interactive communication skills of clinicians, reducing the risk of overestimating an intervention's efficacy due to publication biases[270]. When publishing interventions that are potentially behaviour-modifying, it appears to be especially important to include detailed information, so as to enable following researchers to separate the parts they would like to keep from those they would like to discard in the ensuing development of the field. Hence, publication of negative findings is important to reduce the risk of overestimating the effect of specific interventions due to publication biases[270].

In conclusion, this study does not provide evidence for an effect of a short course on physician information provision with effect on patient recall, and interventions to improve the effectiveness of this medical task should carefully consider the limitations of our intervention.

Questionnaires

The intervention was directed foremost to improve information provision and recall. We hypothesized that it would also improve patient involvement and SDM, measured by CPS and CollaboRATE, and general assessment of the physicians' communication skills, measured by 4HPQ. We did so to look at possible correlations between SDM, recall and adherence. It is a general opinion in the health communication research community that SDM can have a positive effect on adherence, based on some studies [28, 209, 210]. However, it has also been shown that neither patient satisfaction[58, 59], nor SDM[134] are significantly correlated to recall. When we were not able to demonstrate other changes from the intervention than an ability of the physicians to prioritize information, and no effect on recall, a change in such crude measures as these questionnaires was highly unlikely. So it was, and we refrained from further exploration of questionnaires items.

Description and measurement of three information-giving strategies

In paper II, the definitions of how three key strategies we trained the physicians to use, and their operationalization into observable behaviours that can be measured, are the main results. Previous studies do not provide the means to examine the manner in which instructions about medications are communicated[100]. A recent review aiming to systematize verbal strategies for physicians to provide information to their patients pointed out that in a lot of the previous research on communication skills, the information-giving task is described generically and content focused, leaving the physicians little instruction in *how* to concretely manage the task. This review pointed at the possibility of looking to theories consolidated in other disciplines when extracting strategies for verbal information giving[140].

In our study we addressed this lack of theoretically-driven efforts concerning verbal information-giving strategies. To achieve the concretization of the three key strategies, we incorporated theory from linguistics and research on dialogic interaction, and used techniques like microanalysis of video-recorded face-to-face dialogue. By this we were able to validate portioning vs. non-portioning pauses by a significantly increased patient responsiveness, which is in line with previous research[160]. By defining pauses as portioning or not, based on whether they were following a meaningful, information-carrying instalment during which the physician looked at the patient, we brought the sequence and timing of the communicative act into the methodological assessment, as suggested by Cegala et al.[271], instead of looking only at frequency of occurrence. Our findings provide a link from theoretically driven observations to the results of the RCT. It does suggest that achieving effective changes may require more extensive or even more specific training than this short training programme provided, and that taught behaviour-change methods should be theory driven and evidence based[272].

Here I would like to mention an observation: when analysing the pauses, we noticed that the physicians quite often made pauses at places where they did not have a purpose, e.g., in mid-sentence, where it would be unnatural for the addressee to signal either that they are following or are in need of further explanation. It could almost look like the physicians strategically chose to pause at these moments to avoid interruption and keep the turn, while still adhering to the expectation of making pauses. This observation is similar what was found in a previous study showing that simply asking physicians to use a strategy, will not automatically lead to a patient-centred approach[273]. It made me consider the importance of not only telling physicians what behaviour we want them to express during a training, but to make sure that they also gain insight in the background theory of basic interaction physiology explaining the motivation for the behaviour.

Strengths

Properties pertaining to the measurement system Count-COPIN and Count- PROPIN that I consider important: First, it does not categorize or rate content, apart from defining units of information as inside the pre-decided definitions of what to count or not. Second, it can be applied to unscripted consultations that differ in length, content and complexity. Third, the inter-rater reliability was good. Finally, its approach to recall allows for realistic analysis of speech as it occurs in real-life. The patient is not required to repeat the words of the physicians. We designed a system for allowing score of incomplete recollections, generics and specifics, and "gist" understanding. Count-COPIN enables the coder to pick out units of information about medication from the full content of complex unscripted conversation through a series of definitions, and Count-PROPIN enables us to quantify how much of the information the patient remembers even when worded differently.

As mentioned earlier, studies in the field of communication skills training for clinicians tend to be uninformed about insights from other fields, in particular sociolinguistics[274], and research on how physician gaze is used to mobilize patient response[159, 160, 223], or how portioning is used to convey complex information[153, 157]. Our methodology for assessing the three strategies provide a more minute description of behaviour, like a microscope on conversations, outweighing what can be learnt from simple rating systems or questionnaires. That our analyses were based on videotaped interactions, made us able to capture non-verbal dimensions of communication. By developing a method to describe the three strategies in such detail, a stronger link between the teaching intervention, the immediate outcome (behaviour) and the intermediate outcome (recall) was created.

In the RCT, I consider the use of real patients with MS, able to empathize with the fictive situation a strength. That the participating patients really had MS adds an invaluable realism in reactions and motivation. Standardized patients (actors) would not likely have been able to imagine what it is like to have such a Damokles' sword over their heads as such an unpredictable, chronic, frightening and potentially severely debilitating disease like MS is. In addition, the real-time observation of the consultations, together with the use of the Check List, strengthened a realistic cued recall of complex individually tailored information.

Limitations

This study has several limitations, most of them connected to the design of the RCT: First, due to our anticipation of a large effect of the intervention, and the time-consuming nature of the data collection, our sample was too small. Our anticipation of a large effect did not have a strong enough base in theory nor in previous communication skills intervention studies. Second, our outcome measure had to be developed based on data collected in the study. Third, the teaching intervention was not sufficiently informed by insights particularly from sociolinguistics and microanalyses of physician-patient interactions. Fourth, the training intervention was held by the initiator of the study. Fifth, the interviewer was not blinded. Finally, the setting was simulated and not a real clinical encounter.

8. Future perspectives

Count-COPIN makes quantitative description of complex medical treatment information possible in unscripted consultations with information tailored to the individual patient. Count-PROPIN takes into account patient gist understanding, paraphrasing and fragmentary or imperfect comprehension when measuring the patient recall rate. This is a useful complement to previous research on describing patient-physician interaction [97-104]. There are possible uses for this methodology in further studies. Although developed on and for information about medical treatment, it could be redesigned to count other phenomena by careful definitions. Count-COPIN could for example be used to measure how many incorrect UoI's that are given in a specific informative setting, and Count-PROPIN could be used to see whether those UoI's found more important by the physician were recalled more often. The methodology could be adapted to evaluating the effect on patient recall when comparing different information techniques, or when comparing participation in a real-life consultation to watching a pre-recorded consultation or an information video. It could also be used to compare short-term memory/working memory to long-term memory by having different groups with recall interviews at different time intervals[166].

The large amounts of information-containing material we needed to organize made the analysis very time-consuming. We are now living in a time in which computerized methods of processing and analyzing large amounts of natural language data, including contextual nuances, lexical semantics and topic segmentation, are being developed[5]. Computerization of Count-COPIN and Count-PROPIN, specified according to the project needs, would enable fast analysis of large amounts of complex data.

The assessment tools developed in paper II, with background and motivation for each strategy, as well as detailed implementation and assessment definitions, may be helpful for future developers of health care personnel training interventions. The work is a step in the direction towards a more standardized medical communication research framework that incorporate and build on previous findings in other and related fields, e.g., educational psychology and dialogic interaction. The tools we have developed in this work may also be used to describe in more detail how complex medical

[5] *Lexical semantics: the meaning of individual words in context. Topic segmentation: separate text into segments each of which is devoted to a topic, and identify the topic of the segment.*

information is provided in practice today, and contribute to a more consistent methodological approach when testing complex medical information-giving strategies, for which a need has been identified in the field[2].

Finally, working on this project has made me reflect on some of the cornerstone assumptions it rests on. A lot of previous research on improving the clinician factor [50] has been done on outcomes like trust, reduced anxiety and patient satisfaction. But such emotional patient reported outcomes are hard to measure, and do not necessary correlate with the findings of objective observers[58, 59, 275]. Recall is a cognitive and more objective outcome, and a necessity for treatment adherence [50, 134]. Still, the general assumption that the more the patient is able to remember the better, may not be valid in all settings. As previously stated in the Introduction; when measuring recall, we actually measure both understanding and memory. My hypothesis, derived from watching these consultations and performing these interviews, is that when being given complex information about treatment options, the patients intuitively make multiple micro-decisions throughout the information sharing; interpreting, asking for clarifications and weighing information against information until one option appears superior to them. They then seem to make little effort to remember the discarded. *Understanding* the information right then and there is thus more important than recalling it afterwards. The information sharing strategy of checking whether the patient has understood, not just remembers, becomes imperative, as does portioning with meaningful pauses that invite patients to confirm understanding or show a need for clarification.

Another assumption is that in order to demonstrate effects, randomized controlled trials is always the method of choice. I have come to doubt whether there are measurements sufficiently precise, experimental situations sufficiently realistic, and trials sufficiently large to tease out exactly which behavioural elements in what sequence would render a reproducible effect on patient recall (or understanding), well-being, and health in different clinical situations. After all, every consultation is co-constructed between participants here and now[256, 257]. As the philosopher Heraclitus said: “No man steps in the same river twice. Because it is not the same river, and he is not the same man.” The same could be said about encounters.

9. Conclusion

This thesis is based on data collected in one RCT, and reports two new observational tools to study information provision in physician-patient conversations, in addition to the results of the RCT.

The measurement system Count-COPIN and Count-PROPIN makes it possible to measure the number of units of information physicians give patients in unscripted consultations in which the physician is at liberty to adapt their information to the needs of the individual patient. It also enables measurement of the percentage of units of this information that the patients recall, all the while taking into account the imperfect and fragmentary nature of a layperson's verbal presentation. We tested whether a customized intervention could improve physicians' ability to inform patients with MS about treatment escalation. With Count-COPIN we showed that the physicians delivered a significantly lower amount of information units. Using both Count-COPIN and Count-PROPIN, we showed that the intervention did not have effect on patient recall. We then developed a tool that made it possible to reliably assess three key communication strategies we thought important for complex unscripted oral information sharing, that were incorporated in the training intervention. We saw that the physicians did not change their communicative behaviour with regard to these three strategies.

Count-COPIN and Count-PROPIN can be adapted to other clinical conversations involving sharing of complex information. Stringent definitions would be needed, and inter-rater reliability would need to be determined for each such study. The assessment of our three strategies also needs to be validated in future studies.

With this thesis we have shed some light on how to evaluate the connecting steps from a teaching intervention to changed physician behaviour, and further on to a patient outcome. This may teach us and future researchers that there is no shortcut around detailed description and definition of the behaviours we wish to improve, if we are going to be able to measure such improvement. The best solutions are found by applying a complexity lens to our work, not by simplifying it. Future studies on communication training need to identify clearly which outcomes they are pursuing. The basic research on how to improve communication to achieve the desired outcomes needs to be solid and include fundamental dialogic interaction physiology. The methods for testing further training needs to be consistent and reliable.

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Appendix A

APPENDIX to "Three strategies when physicians provide complex information in interactions with patients: how to recognize and measure them".

I. The definitions used for operationalizing the four communication-enhancing strategies.

1. Mapping the patient's preferences and needs
2. Portioning information
3. Checking for understanding

II. Slice methodology

I. The definitions used for operationalizing the three communication-enhancing strategies.

1. Mapping the patient's preferences and needs

The strategy of eliciting the patient's current understanding and pre-existing medical knowledge of their disease and treatment, as well as their information needs and preferences, with the intention of utilizing the response to tailor the level of information giving[1, 2].

Since we are quantifying these skills in order to count how often each physician uses the strategy, every topic they ask about needs to be counted separately, even if more topics are mentioned in one utterance. Here is an example of multiple questions grouped together: I-36, line 171-172: "Hva har du selv gjort deg noen tanker om, rundt, rundt forskjellige alternativer? Har du hørt om noen alternativer selv, eller kjenner du noen som har hatt noe annet enn Tecfidera?» (What kind of thoughts have you had yourself of, about, about different options? Have you heard of any alternatives yourself, or do you know anyone who has had anything else than Tecfidera?)

The definition includes:

- Asking for the patient's thoughts around:
    - current situation, practical and otherwise
        - E.g. I-16; "Er det noe du foretrekker tabletter du, eller? Foretrekker du injeksjoner?» (Is it that you prefer pills, you, or? Do you prefer injections?)
        - E.g. I-7 line 289; «vad tenker du om det? (ja altså ee) sier det her [om] MR-en (og sånn) (eller e)» (What are your thoughts about that? (well, you know ee) talking about the MRI (and so on) or eh))
    - current treatment
        - E.g. I-22, line 55 «Jeg vet ikke hva du tenker rundt, rundt det?» (I don't know how you feel about, about that?) [After discussing how current drugs may not be efficient enough.]
    - a change of medication, knowledge/thoughts.
        - E.g. I-9 line 91-92. "Nei, det er jo en vurderingssak det da om man skal endre, ehm, behandling eller ikke, eh, hva tenker du selv om det alternativet?» (No, whether to change, ehm, treatment or not, would then be a matter of consideration, eh, how do you feel about that option?)
        - E.g. I-17 page 2. "Hva, hva har du hørt om, om type andrelinjemedisiner fra før?" (What, what have you heard about, about second line drugs?) [Would influence the amount and level of information given.]
        - E.g. I-2 line 110-112. «Det ene er Gilenya. Har du hørt om..?» (One is Gilenya. Have you heard about..?)
    - possible pros/cons/effects/risks with new treatments
        - E.g. I-15 line 145-146; "Hva tenker du om bivirkningene da, av den nye behandlingen? Tenker du at det er til å leve med, eller?» (What are your thoughts about the side effects, of the new treatment? Do you think they are possible to live with, or?)
        - E.g. I-16 line 76, «Det sier kanskje ikke så mye?»(That may not tell you much?) [After telling the patient they have JC-virus.]
        - E.g. I-17 line 245, «Men hva tenker du om, om Gilenya da?» (How do you feel about, about Gilenya, then?)
    - current test results or findings

- E.g. I-21 line 21; «Ja. For det har ikke du fått høre før?» (Yes, Cause you haven't heard that before?) [After telling the patient that results from MRI and blood tests are in.]
- E.g. I-10; line 27; «har du noe spørsmål i forhold til det sjøl?» (Do you have any questions concerning that?)

- Explicitly asking the patient what he/she wants do know/ are interested in information about.
  - E.g. I-21 line 310; "du er interessert i hva bivirkningene er.» (You are interested in what the side-effects are.)
  - E.g. I-23 line 82; «Ehm, jeg vet ikke om du vil høre litt om de..» (Ehm, I don't know if you want to hear a little about those..)

- Asking about the patient's medical knowledge
  - E.g. I-22 line 148. "Du er sykepleier, jobber du innen nevrologi?" (You are a nurse, do you work in neurology?") [Would influence choice of lingo, perhaps also level of perceived medical understanding])
  - E.g. I-1 line 178. "Kjenner du noen som bruker det?» (Do you know anyone who uses that?) [Gilenya]

- Making sure that the information gathered from the patient about her wishes and preferences is correct. (Important because the overall function of checking for pre-understanding is to influence what the doctor should provide information about… so a patient preference should affect what the doctor informs about.)
  - E.g. I-22 line 158-160; «Ehm, har du, du, du, hvis jeg forstår deg rett så har du selv ikke noen preferanse ovenfor medikamentet, annet enn at du har hørt at Tysabri er bra, men det betyr nødvendigvis ikke at du, at du på en måte ønsker Tysabri for enhver pris» (Ehm. Have you, you, you, if I understand you correctly, you have no personal preference about the drug, except that you have heard that Tysabri is good, but that doesn't necessarily mean that you, that you sort of want Tysabri no matter what)
  - E.g. I-26 line 64-65; «Men da er du på en måte litt sånn, tenkt litt at det å bytte medisin det er kanskje det beste for deg da?» (But, then you are sort of like this, been thinking that a change of medication might be best for you, right?)

- The physician summarizes information the patient has given. If there is an element of probing for more information, it is included. If it is merely a summary, it is a formulation and is excluded, see below.

- E.g.. I-1 line 42+44: «For det er bildene du tenker mest på?» (Because you are mainly thinking about the images?)

Definition does <u>not</u> include

- Questioning the patient about:
  - Current symptoms, side-effects, medication
  - Possible child wish
  - Family medical history
  - Own medical history
  - Previous tests

  (Clarification: Of course, the above topics are also important for the physician and could and should be asked with the intention of utilizing the response to tailor their own information-giving. **But it is not exploring the patients' understanding .** If the physician asked the patient if a stated child wish had made her feel more restrictive about medication, or if previous side-effects affected how she would choose today, this would be included in the definition. But it has to be about the patients' views or understanding, not just questions about facts.)

- Physician reacting to patient volunteering information with repetition <u>only</u>. (Term: formulation)
  - E.g. I-16 The patient responds to the physician. mentioning Tysabri and Gilenya by saying: "De har jeg hørt om begge to.» (I have heard of both of those.) The physician responds "Du har hørt om begge to?» (You have heard of both of those?) [In the next sentence the physician expands on this by asking «Hva vet du om de?" This, on the other hand, is a checking for pre-understanding.]
  - E.g. I-2 Line 114. [line 110-113 included for context. «Det ene er Gilenya. Har du hørt om..?» (One is Gilenya. Have you heard about..?) The patient answers «ja.»(yes)]
  - Line 114: «Du har hørt om den? Ja?» (You've heard of it? Yes?) Line 114 is a formulation confirming the statement above, and is not counted as checking for pre-understanding.

- Small talk.
  - E.g. I-26 "Du er litt spent kanskje?" (Perhaps you are feeling a little tense?)

- The physician summarizes information the patient has given. If it is merely a summary, it is a formulation and is excluded.
  - E.g. I-36, line 189 "Men om jeg nå forstår deg rett så kjenner du, ut i fra det som har vært, at Tecfidera, og det jeg har fortalt om MR-bildene og sånn, Tecfidera ikke virker å fungere tilstrekkelig og du inne i dine tanker på å prøve å bytte til noe som fungerer bedre og som

er mer effektivt helst.» (But if I understand you correctly, you feel, based on what has been, that Tecfidera, and what I have told you about the MRI-images and so on, Tecfidera does not seem to have sufficient effect and you are considering trying to change to something that works better and that hopefully is more efficient.)

- Questions posed <u>after</u> giving the main body of information to find out if the patient leans towards a preferred choice.
    - E.g. I-21 “Jeg vet ikke hva du tenker? Ja, det er jo ikke sånn at du må ta noe sånn endelig stilling.» (I don’t know what you are thinking? It is not like you have to make some kind of final decision.)
    - E.g. I-7 line 659-661«ja. (.) kan jeg bara helt kort spørre (.) vad kjenner du så spontant (.) ee mellom å fortsette litt til på den medisinen du står på, eventuelt å vurdere litt til (.) eventuelt få litt mer tenke (.) tid? (1) eller å bestemme å skifte i dag.» (Could I just ask very briefly. How do you feel spontaneously eh between continuing a little longer with the medication you are on, perhaps giving it some more thought, perhaps having some more time to think? Or making a decision to change today.)
    - E.g. I-13, line 138; «Men nå har jeg lagt litt ut for deg, hva tenker du om disse, har du endret noe mening eller er du..» (But now I have lectured some for you, what do you think about these, have you changed your mind, or are you..)

- Questions posed after giving information, checking if the patient is listening/following. This falls under the area of checking for integrated understanding. If it is just a yes/no question, it is however not good enough, and excluded from the definition of checking for integrated understanding.
    - E.g. I-14 line 160. “Er du med, henger du med?» (Are you following?)

- Questions posed as part of closing sequence.
    - E.g. I-22 page 8; “Eh, er det noe du lurer på rundt disse tingene?» (Eh, are you wondering about anything concerning these things?)
    - E.g. I-7 line 747; «det var ikke noe du brinner inne med nå da?» (there’s nothing you have left unsaid, now?)
    - E.g. I-35 line 344; «er det andre ting som du, du lurer på, med disse medisinene» (are there anything else that you, that you want to know, about these drugs)

2. Portioning information

Physicians were encouraged to *portion* information when presenting it to patients. "Portioning" refers to stating information in short, understandable units followed by a brief silence, which offers the patient an opportunity to respond.

- Example [P35-Dr4] 7:03.27-7:15.23

In this example, the doctor contributes information about the drug Thyroxine. The physician pauses in between short instalments of information. (Note the example presents only the doctor's speech, in Norwegian, with an English translation in italics):

1. D: (og) det må man nesten regne med, /**0.89 s**/ men det vil jo /**0.95 s**/
1. *(and) you almost have to be prepared for that, /**0.89 s**/ but it will /**0.95 s**/*
2. tyroksin er jo ikke noen /**0.34 s/** altså /**0.60 s**/ det er ikke det er ikke noe veldig /**0.75 s**/
2. *you know, thyroxine is not /**0.34 s**/ a /**0.60 s**/ it's not it's not any very /**0.75 s**/*
3. veldig alvorlig å få det, man blir avhengig av den tabletten? /**0.54 s**/
3. *very serious thing to get, you become dependent on that pill? /**0.54 s**/*

This is an example of what we saw the physicians do. But to achieve patient involvement and patient feedback, all pauses are not equal. The pauses need to follow a meaningful instalment of information, it cannot just be the physician coughing or considering. In addition, literature shows that response is invited when the physician looks at the patient during a pause[3, 4].

Based on this we have looked for a specific use of pauses in the material, named portioning.

To achieve portioning we need the three following ingredients:

1) <u>The pause needs to be short:</u> Definition: >0.3 seconds

2) <u>The pause should follow a meaningful unit of information:</u>

   We split the pauses over 0.3 sec in the material in two groups:
   - "mid pause" = one that happens in the middle of a sentence, the meaning of the sentence is not clear at that point. (Breathing, thinking, looking for a word, speaking slowly).
   - "end pause" = one at the end of a meaningful utterance. Hints in the prosody/intonation that the utterance is complete, and the information in it is fully interpretable.

3) Physician looking at the patient

Definition: An “end” pause, > 0.3 seconds, in which the physician is looking at the patient.

- Example from video no 22, exempt from slice 09:00-10:00, in Norwegian, with an English translation in italics.

> Lege: Ehm /mid/, så /mid/, så når vi skal vurdere hvilket preparat du skal ha, så ville jeg kanskje ikke sett så mye på, på effekten /***END***/, eh, men kanskje mer på andre faktorer /end/. Ehm.. du har jo allerede vært inne på at to av disse midlene gis /mid/ intravenøst../***END***/
>
> *Physician: Um /mid/, so /mid/, so when we are considering which treatment you should have, I probably would not look that much at, at the effect /**END**/, um, but maybe more at other factors /end/. Um.. you have already mentioned that two of these drugs are given /mid/ intravenously../**END**/*

In the example above, we have two instances of collaborative portioning marked with **/END/.**

Figures 2 and 3 show the ELAN annotations that accompanied a pause deemed as portioning (when the physician was looking at the patient) and a pause that was deemed non-portioning (when the physician was looking away from the patient).

Figure 2. Physician looking at the patient

Figure 3. Physician looking away from the patient

3. Checking for understanding

The strategy of checking whether the patient have received and understood the imparted information by encouraging the patient to actively explain or summarize information the physician considers important has been shown to be effective for increasing patient retention[5]. The question should specify the topic.

Definition includes

- Explicitly asking the patient to rephrase, explain or summarize information.
- Explicit questions to check if the patient remembers.
    - E.g. I-17 «Husker du de medisinene vi har snakket om i dag?» (Do you remember the drugs we talked about today?) and «Husker du noe av bivirkningene til, til medisinene?» (Do you remember any of the side effects of, of the drugs?)

Definition does <u>not</u> include

- Small talk
    - E.g. I-26 "Du er litt spent kanskje?" (Perhaps you are feeling a little tense?)
- Questions posed after the main body of information giving to find out if the patient leans towards a preferred choice.
    - E.g. I-21 "Jeg vet ikke hva du tenker? Ja, det er jo ikke sånn at du må ta noe sånn endelig stilling.» (I don't know what you are thinking? It is not like you have to make some kind of final decision.)
- General yes/no questions (that don't specify the topic):
    - E.g. I-14 line 160. "Er du med, henger du med?» (Are you with me, are you following?)
- Questions posed as part of closing sequence.
    - E.g. I-22 page 8; "Eh, er det noe du lurer på rundt disse tingene?» (Eh, do you have any questions concerning these matters?)
- The doctor summarizing information for the patient.
    - E.g. I-30 lines 235-238 "Ok. Så oppsummere; Tysabri utmerket medisin, infusjon en gang i måneden, men problemer med JC-viruset. Veldig lav risiko de første to årene, men nivået av antistoffer kan stige og da er risikoen høyere og uansett må man gjøre holdt og front etter to år.» (OK. Then summarizing; Tysabri excellent drug, infusion once a month, but problems with the JC-virus. Very low risk the first two years, but the level of antibodies may rise and then the risk would be higher and you would have to stop after two years anyway.)
- Questions that project an affirmative answer
    - E.g. I-30 line 21. «Fikk du med deg dette her? Greier jeg å si det på en fornuftig måte sånn at du husker noe av det?» (Did you get his? Am I able to say this in a comprehensible manner so that you remember any of it?)

II. Slice Methodology: a more extensive description of how we approached it:

The 34 consultations ranged in duration from 7 to 29 minutes, with a mean of 20 minutes. Roter et al. demonstrated that one-minute slices of medical interaction show a consistent, moderately strong pattern of correlation with full-session interaction[6]. To study each physicians' use of pauses during information-giving sequences, we therefore extracted a one-minute stretch of information-dense sequences from each video. We found that such density usually took place approximately seven minutes into the consultation, thus we proposed using the first one-minute extract from that point. If this extract did not contain a minimum of three utterances of information-giving, we shifted one-minute forward, continuing to do so until a high-density information minute was found. (To check the consistency of the pattern of the interaction, we also analyzed one additional minute of information delivery from both consultations of three physicians (i.e., six interviews). For these interviews, we chose a consistent topic (a medication option) rather than a particular time, extracting a total of one minute of information provision utterances about the drug alemtuzumab.)

We confirmed the consistency of the pattern of the interaction in the slice methodology by analysing one additional minute of information delivery from both consultations of three physicians (i.e., six interviews). We also were able to test the consistency between two slices from different parts of the consultation (time vs. topic), indicating that the initial slices extracted were indeed representative of the whole encounter[6].

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Appendix B

Coding System for
Counting Complex Orally Provided Information and Patient Recall

Count-COPIN: Counting Complex Orally Provided INformation

Count-PROPIN: Counting Patient Recall of Orally Provided INformation

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Introduction

Physician engage in information transfer as a huge part of their communication with patients, both to learn facts about their patient, find out about their problems and symptoms, but also to educate, and impart knowledge and treatment advice.

Attempts have been made to study the effect of transferral of information, but no one has yet developed a reliable method of quantifying this phenomenon in unscripted consultations in which complex information transferral is necessary.

As providing information is a required and comprehensive part of medical encounters today, training physicians in how to do it efficiently is necessary. To evaluate training interventions, we need to be able to evaluate complex information uptake reliably, with data both from the encounter itself, and from patients thereafter. Hence, we needed to develop a method to do so.

This work aimed to describe the qualitative development of an information transfer measurement (ITM) coding system; a set of coding criteria for quantitative measurement of transfer of oral information from physician to patient in a complex clinical consultation.

The object of this manual is to describe a method of measuring the transfer of orally given information from physician (or other health care personnel) to patient; by a two step- method, first by identifying and counting all unique and meaningful units of information given by the physician during a consultation; then by identifying and counting the corresponding information units recalled by the patient in an immediately following interview.

Thus, we are able to find the proportion of information given that is actually absorbed and recalled by the patient.

General coding instructions using Count-COPIN and Count-PROPIN

2-STEP APPROACH

We advise a 2-step approach. It is imperative that the coder have read the entire manual before starting.

Step 1: The coder seeks to identify and count all unique and meaningful units of information presented by the physician, using the rule-set outlined in Count-COPIN (Counting Complex Orally Provided Information)

Step 2: The coder seeks to identify and count all unique and meaningful corresponding units of information recalled by the patient, using the rule-set outlined in Count-PROPIN (Counting Patient Recall of Orally Provided Information).

$$\frac{Count{-}PROPIN\ result}{Count{-}COPIN\ result} \text{ x } 100 = \text{recall percentage}$$

WHAT TO COUNT?

As a coder, you need to define what you want to measure, and what kind of data you will need to collect to achieve this. This will of course vary according to what kind of research you are partaking in. It is necessary to make overall decisions in advance on what to include and what to exclude, to keep the material from becoming too large and impossible to handle.

In the study we used to develop this method of measuring the transfer of orally given information, we chose the possible initiation of second line Multiple Sclerosis (MS) treatment as case due to its extreme information complexity and high inherent uncertainty. MS patients currently on no or first line treatment were instructed to imagine having had a history of new attacks, before fictively having had an MRI and blood samples taken. They patients then consulted with a neurologist to receive information about these fictive test results and discuss the choice of further treatment. Immediately after the consultation, a researcher conducted a patient recall interview. Consultations and interviews were videotaped and transcribed verbatim.

During the development of the coding criteria, we chose to only count information pertaining to the following three second-line Multiple Sclerosis-medications; Lemtrada, Tysabri and Gilenya. This is reflected in the inclusion criteria in chapter 2, 1) A and the exclusion criteria in chapter 2, 2). If you wish to focus on a different informational content, you need to adapt these criteria accordingly.

To ensure reliability between coders, follow the rules given in Count-COPIN and Count-PROPIN.

Count-COPIN: Counting Complex Orally Provided Information

Method of identifying all unique and meaningful information units about relevant medication presented by a physician in dialogue with a patient.

1. INCLUSION OF INFORMATION

1.1. We include the following information about the three drugs we wish to count information about:

1.1.1. Reasons for use

1.1.2. Effects

1.1.2.1. This includes working mechanisms.

1.1.3. Side effects

1.1.3.1. This includes counting information about blood testing for JCV-antibodies and the risk for progressive multifocal leukoencephalopathy (PML) a positive test implicates.

1.1.4. Prerequisites for use including up front testing, procedures etc.

1.1.5. Precautions

1.1.6. Administration

1.1.6.1. Infusion, injection, oral, suppository, others

1.1.6.2. Frequency

1.1.6.3. Dosage

1.1.6.4. Place

1.1.7. Recommendations

1.1.8. Comparisons

1.1.8.1. Equal information about two or more drugs provided in the same sentence.

E.g.: «Both drugs have clearly beneficial effects» (said about Gilenya and Lemtrada, which is clear from the context).

The information is:

→ Both drugs [a] 1p

→ have beneficial effects [b] 1p

= Count 2 points

1.1.8.2. Comparative information about two or more drugs provided.

E.g.: Interview 32 (I-32): «about Gilenya, it is also very effective, but Tysabri seems likely to have a somewhat better effect»
Count 2p; 1p for the information that Gilenya is effective, and 1p for Tysabri being seemingly more so than Gilenya. Do NOT in addition count 1p for Gilenya being less effective than Tysabri. However, be aware that the patient may recall the information in this manner.

1.1.9. General statements or characterizations of two or more of these drugs

1.1.9.1. Information about two or more medications as a group

E.g.: I-19: «All three treatments are well documented and efficient»
When the information is given as a group, we count it as a group; 1p for «all three», 1p for «well documented», 1p for «efficient».

1.2. We count all meaningful/useful information.

1.2.1. We have found that the only possible way to count the information reliably is to break it down in to as small units as possible while still maintaining useful information.

E.g.: «One option is Tysabri, which you get in a hospital as a monthly infusion. »

Here we are exemplifying how to break the statement into countable units of information:

→ One option is Tysabri [a] – *option 1p*
→ In a hospital [b] – *administration place 1p*
→ infusion [c] – *administration manner 1p*
→ monthly [d]- *administration frequency 1p*
= 4p

1.2.2. For a unit of information to be useful, it needs to contain a subject, a verb, and at least one of the following; object, complement, or adverbial. This limits the size of our units of information.

E.g.: I-19 «So it is sort of the three main treatments that are relevant»
Underneath we are exemplifying two different ways of breaking the statement into countable units of information:

Example 1.

→ three main treatments are relevant [a]-*general statement, no. of relevant main treatments* 1p

If we try to break it into smaller pieces, we could get something like this:

Example 2.

→ three [a]- 1p
→ main [b]- 1p
→ relevant [c] -1p

But all of them would be useless information on their own. That is why we give only one point, like in example 1.

1.2.3. Still, there can be more than one unit of information hiding in one clause. The ideational content of a clause can involve four types of constituent that: processes (actions/ events/ states), participants (persons/ things/ abstractions), qualities/ states/ features pertaining to the participants, and circumstances (time/ manner/ place/ reason, etc.) of the process and the participants.[1]

E.g.: I-27 «Gilenya is a pill, which you take daily. » Here we are exemplifying how to break the statement into countable units of information:

→ Gilenya [a] – option (participant) 1p
→ Is a pill [b] – administration manner (quality) 1p
→ Which you take daily [c]- administration frequency (event) 1p
= Count 3 units of information 3p

In all the examples above, a point has been given for the name of the medication as the «participant". A point for the information of the name «Gilenya", however, will only be given once throughout the entire transcript. It is necessary to avoid double scoring for repeated information. This will be addressed below in Count-COPIN 3.2.1.

1.3. If the information is incongruent within a statement or with a previous statement, both units of information are to be counted; unless the doctor obviously corrects herself, see example in Count-COPIN 3.4.1.

1.4. When both generalized and specialized information are presented, they are counted separately.

1.5. When the doctor confirms, denies or corrects a statement or question from the patient, this is to be counted as information provided.

2. EXCLUSION OF INFORMATION

These exclusions are specifically tailored according to the study used for developing this manual. If you want to count different information, you need to adapt these criteria accordingly.

The transcriptions we worked with when developing this coding system stem from standardized consultations between neurologists and MS patients about initiating second-line treatment, with focus on the three most common options in Norway at the time. The patients were told to imagine that they had deteriorated on the treatment they were currently receiving.

2.1. We exclude non-medical information or information unrelated to the three drugs we have chosen to focus on.

2.1.1. All information that could not be specifically assigned to one or more of the three drugs we have chosen to focus on is to be excluded

E.g.: I-19 «there are a lot of new medications, which makes the choice more difficult, since we have a lot to choose from»
Deemed to be too general statements, and nor specifically referring to our three chosen medications.

E.g.: I-30 «So, in reality we have three options. » - 0p
No points for the doctor in this example, as the three options will be mentioned and scored for separately. The patient however will get points for remembering that there were three options, if he or she does not remember the separate options.

2.1.2. All information referring just to the term second-line treatment is to be excluded.

Reason: to make the body of information manageable within a reasonable time frame.

E.g.: I-24 «Generally, second-line treatment is more effective than first-line treatment, right? »

2.1.3. All information involving Tecfidera and stem-cell treatment is to be excluded.

Reason: The interviewer does not ask the patient about recollections of this information.

2.1.4. All information about failure of previous medication (first-line medication), as well as information about MRI or clinical progression is to be excluded.

Reason: The information is fictive, and the recall interviewer does not ask about recollections of this information.

E.g.: I-5 «from what we gather from the pictures, and from how you have been the last year, it seems like the treatment you have had, has been a little too inefficient for you, »

2.1.5. Information about having taken a blood sample is to be excluded.

Reason: This is something the patient already knows, and the interviewer does not ask about. The result of the sample is relevant information that is to be included in the counting, but not the statement that the sample has been taken/results are present.

E.g.: I-23 «Um, first I need to tell you that we have also received the result of that blood sample, which is important to consider here, that is, that you are positive to the JC-virus... this index. »

→ I need to tell you – too general, not medical information -0p
→ We have received a result of the blood sample – information already known and not to be counted 0p
→ Important to consider – side effects 1p
→ You are positive - side effects 1p
→ JC-virus – side effects 1p
→ Index – side effects 1p
= Count 4 units of information 4p

2.2. We exclude too general information.

2.2.1. Information that is too general to be deemed medical information is to be excluded.

E.g.: I-30 «It is important that you are familiar with the treatment» Deemed general conversation, not medical information, thus not to be counted.

2.3. We exclude information without sufficient contextual anchorage, e.g. utterances that cannot contextually be assigned to specific drugs

2.4. We exclude ambiguous information.

2.5. We exclude start-up information related to the design of our study.

1. Practical start-up information encompasses fictive plans to meet again at a certain interval, letters, brochures and planned follow-up phone calls or contact with other health-care personnel, etc.
Reason: Fictive future plans are not relevant for the patient to remember. The interviewer does not focus on this information during the recall interview.
E.g.: I-22 «, and that we will talk again in about two weeks. » -0p

2. Practical start-up information does not encompass specific examinations or tests that are needed in order to start with a new medication. This falls under Count-COPIN 1.1.4. «Prerequisites for use» or 1.1.5. «Precautions».

3. OTHER PROBLEMS

3.1. Equality of units of information

3.1.1. We do not rate or discriminate according to the perceived importance of the information.

3.1.2. We do not rate or discriminate according to the perceived correctness of the information.

3.1.3. We do not rate or discriminate according to the perceived quality of the information.

3.2. Repetitions / information with similar meaning: It is necessary to avoid double scoring for repeated information in the entire consultation. The coder needs to have this in mind and check for repetitions not only within a sentence, but also throughout the transcript.

3.2.1. If the repetition gives precisely the same information, do NOT count.

E.g.: I-27 (abridged) «The thing with Gilenya is that it may slow the heart rate. »

→ Gilenya [a] – option (participant) 1p

→ may slow the heart rate [b] – side effect (quality) 1p

= Count 2 units of information 2p

This affects the counting in the following sentence in the transcript:

E.g.: I-27 «Gilenya is a pill, which you take daily. »

Here we are exemplifying how to break the statement into countable units of information:

→ Gilenya [a] – option (participant) /<u>REPETITION</u>

→ Is a pill [b] – administration manner (quality) 1p

→ Which you take daily [c]- administration frequency (event) 1p

= Count <u>2</u> units of information <u>2p</u>

3.2.2. If the repetition gives precisely the same information, even if with other words, do NOT count.

E.g.: I-33 «Also, everyone gets a rash... heh, 98 % get a rash, that is, only while receiving the treatment»

→ Also, everyone -[a] 1p

→ gets a rash... [b] 1p

→ heh, 98 % [c] *correction - no extra point*

→ get a rash [d] *repetition – no extra point*

→ that is, only while receiving the treatment [e] 1p

= 3p

Then when we look at some other related statements in I-33: «that is associated with that treatment only... » and «but it is temporary»

→ that is associated with that treatment only... *Repetition of information [e] though in other words - Count no additional point.*

→ but it is temporary - *Repetition of information [e] though in other words - Count no additional point.*

3.2.3. If the repetition gives a somewhat added or altered information, count.

E.g.: I-33 «Also, everyone gets a rash... heh, 98 % get a rash, that is, only while receiving the treatment»

→ Also, everyone -[a] 1p
→ gets a rash... [b] 1p
→ heh, 98 % [c] *correction - no extra point*
→ get a rash [d] *repetition – no extra point*
→ that is, only while receiving the treatment [e] 1p
= 3p

In another sentence in I-33: «yeah, I think it is a so-called generalized rash, »

→ generalized rash [a] 1p *added information*
= 1p

3.2.4. If the repetition states the same in an easier or more general manner than previously provided, do NOT count.

E.g.: I-19: «And that is close to 50%, so that is a good share »

→ close to 50% [a] 1p
→ that is a good share [b] *repetition/simplification – no extra point*
= 1p

E.g.: I-19: «But if you have, for example, are very strongly positive and have used it for many years, then it will increase from 3 per 1000 up to 10 per 1000 every single year so that would be many times higher»
This is also a good example on how to break the statement into units of information:

→ If you are very strongly positive [a] 1p
→ and have used it for many years [b] 1p
→ then, it will increase [c] 1p
→ from 3 per 1000 [d] 1p
→ to 10 per 1000 [e] 1p
→ every single year [f] 1p
→ so that would be many times higher [h] 0p We see [h] as a *repetition/simplification of the information in [d] and [e]– no extra point*
= 6p

3.3. «If, then» – expressions

3.3.1. Count the units of information, but do not in addition count the whole. (In Count-PROPIN on the other hand, the patient may be awarded points both for understanding the whole and for remembering loose units of information.) So, no extra point for the «if, then»-relationship between the two statements in Count-COPIN.

E.g.: I-19 «Worst case scenario, if your metabolism becomes chronically low, you will need to take pills to get up on a normal level. »

→ Worst case scenario -[a] 1p
→ If your metabolism becomes chronically low [b] 1p
→ You will need to take pills [c] 1p
→ to get up on a normal level [d] 1p
= 4p

3.4. Corrections

3.4.1. If the physician provides information, then later explicitly corrects her/himself, count ONLY the last version of the information.

E.g.: I-33: «Also, everyone gets a rash... heh, 98 % get a rash…»

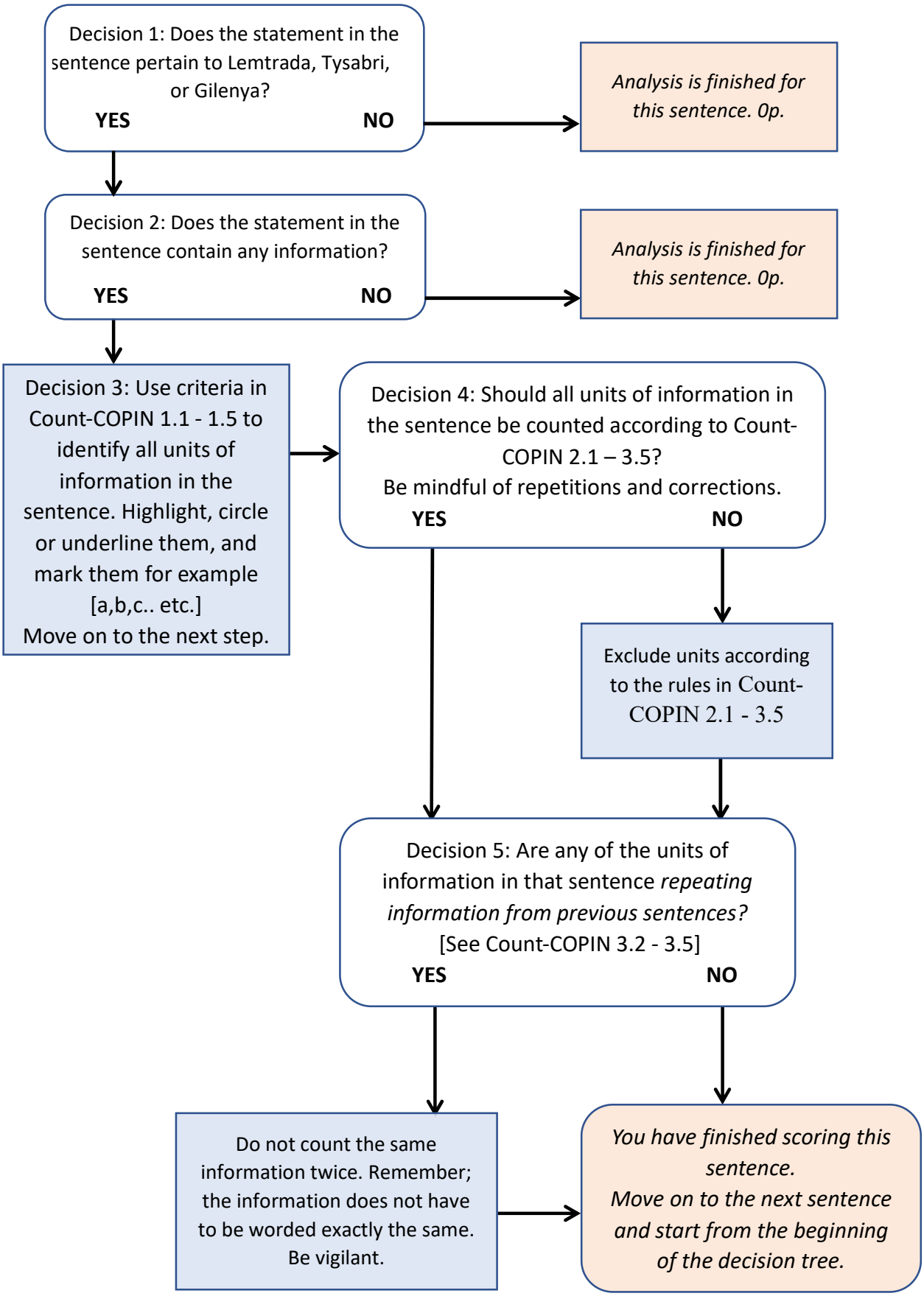
→ rash [a] 1p,
→ everyone [b] 1p.
→ heh, 98 % The *physician corrects herself, see* [b]. *Count no additional point. The information of 98% stands.*
→ get a rash *Repetition of* [a]. *No additional point.*
= 2p

3.5. Information provided with words of low specificity.

3.5.1. Evaluate the distinction between the words and do not count excessively

E.g.: «You will feel weak, indisposed, knocked out". =1p

Decision Tree for analysis of the information provided by the doctor, sentence by sentence.



Count- PROPIN: Counting Patient Recall of Orally Provided INformation

Method of identifying all unique and meaningful corresponding units of information recalled by the patient, following orally provision of information about relevant medication by a physician.

To use Count-PROPIN we assume that the coder has already used Count-COPIN, thus having already defined the units of information provided and counted them.

1. Be liberal in favor of the patient when in doubt.

There is a theory that doctors in general give too much information. To ensure that we do not design the measurement tools to reinforce our own prejudices, we wish for the coders to be liberal in favor of the patient.
When the patient recalls, the words will often be somewhat rephrased, generalized and altered. If the coder's interpretation is that the patient has grasped the message and is able to rephrase it, we give points liberally.

E.g.: I-19 «So it is sort of the three main treatments that are relevant»

→ three main treatments are relevant[a] -*general statement, number of relevant main treatments*

-0p for the doctor in this example, because the three relevant options were mentioned and scored for separately. (See Count- PROPIN 3.2 below)
(1p would have been counted for the doctor mentioning that there are three options - if the three options had not been scored for separately.)

When the patient recalled this, in this example, she said: «There were three options here."

→ three options 1p.

2. COUNT 0/1 (zero/one possible) if

2.1. The patient attributes the information to the wrong drug.
  2.1.1. Exception: See «Avoid downstream errors" below in Count-PROPIN 3.3.
2.2 The patient is not able to provide a clear response.
2.3 The patient demonstrates lack of understanding of information
2.4 The patient says s/he doesn't remember
2.5 The patient is clearly guessing.

3. COUNT n/n (number of units/number of units possible)

1.1. Correct patient recall of any bit of information provided and counted using Count-COPIN

3.2. Generalized vs. detailed recall.

1.2.1. Situations: The doctor provides a list of side effects. The doctor informs about how many side effects there are, before giving detailed information about each option.

All items on a list that the patient recalls will count as 1p. each.

If the patient remembers a common denominator, e.g.: «there were plenty of side effects", this will count as 1 point.

If the patient remembers a common denominator AND individual items on the list, the recall of the common denominator will only earn a point as long as the patient does not remember more than two individual items on the list.

If the patient remembers three or more side effects AND says: «there were many side effects", score NO additional point for the latter.

E.g.: The doctor says «you will have to do monthly (1) blood (1) and urine (1) tests, where they check for blood platelets (1) and thyroid function (1), and also an MRI scan (1) biannually (1)" - total 7p.

→ Alt. 1) The patient recalls «there was a lot of follow-up" –1p
→ Alt. 2) The patient recalls «there was a lot of follow-up, like blood samples" –2p
→ Alt. 3) The patient recalls «there was monthly (1) blood (1) and urine (1) tests and an annual MRI scan (1)" – total 4p
→ Alt. 4) The patient recalls «there was a lot of follow-up, there was monthly (1) blood (1) and urine (1) tests and an annual MRI scan (1)" Give no additional points for the generalization, as the patient recalled more than two items from the list – total 4p
→ Alt.5) If the patient recalls all items on the list -total 7p.
→ Alt.6) If the patient recalls all items on the list + says that there was a lot of follow up-total 7p.

1.2.2. Avoid counting a unit of information more than once.

E.g.: If the patient recalls that there were three options, and then proceeds to mention all three options, (s)he should not get a point for the first answer. If (s)he only remembers two of the options, but remembers that there existed a third, this point is relevant to count.

1.2.3. The patient remembers a generalization from many things the physician has said.

E.g.: The physician explains in great detail about the patient carrying a low level of a virus antibody in their body, and that there is a risk that using Tysabri may reactivate this virus and lead to a serious brain infection. The level of these antibodies may increase, which would increase the risk of this dangerous side effect.

I-4: The patient recalls «there was something about some antibodies »

The patient should get 1 point for remembering that the antibodies were mentioned.

1.2.4. «If, then" – expressions: The patient may be awarded points both for understanding the whole and for remembering loose units of information.

E.g.: I-19 «Worst case scenario, if your metabolism becomes chronically low, you will need to take pills to get up on a normal level. »

→ Alt. 1) The patient recalls «worst case, you had to take pills» –2p
→ Alt. 2) The patient recalls «It could affect your metabolism" –1p
→ Alt. 3) The patient recalls «worst case (1) low metabolism (1) treatable (1) with pills (1)" – total 4p
→ Alt. 4) The patient recalls «If things got really bad, you could end up having to take other pills for this» If-then (1) pills (1) – 2p

3.3. Avoid downstream errors.

3.3.1. We do not want real transfer of knowledge to be camouflaged as downstream errors. E.g.: A patient cannot initially remember the name of a drug, but s/he recalls how the different drugs were administered. Interviewer and patient agree to refer to the drug as «the second drug". The patient recalls multiple units of information about the drug. The patient should get the adequate points for this.

2. The ideational content of a clause

4.1. When the coder is working with the task of identifying the primarily given information in the transcript of the post-consultation interview with the patient, we advise the coder to look for the ideational content of a clause. This can involve four types of constituents: processes (actions/ events/ states), participants (persons/ things/ abstractions), qualities/ states/ features pertaining to the participants, and circumstances (time/ manner/ place/ reason, etc.) of the process and the participants.[1] These categorizations can be used as an additional tool by the coder as an aid to help single out the units of information.

E.g.: Count-COPIN [I-27-47] «Gilenya is a pill, which you take daily. » Here we are exemplifying how to break the statement into countable units of information:

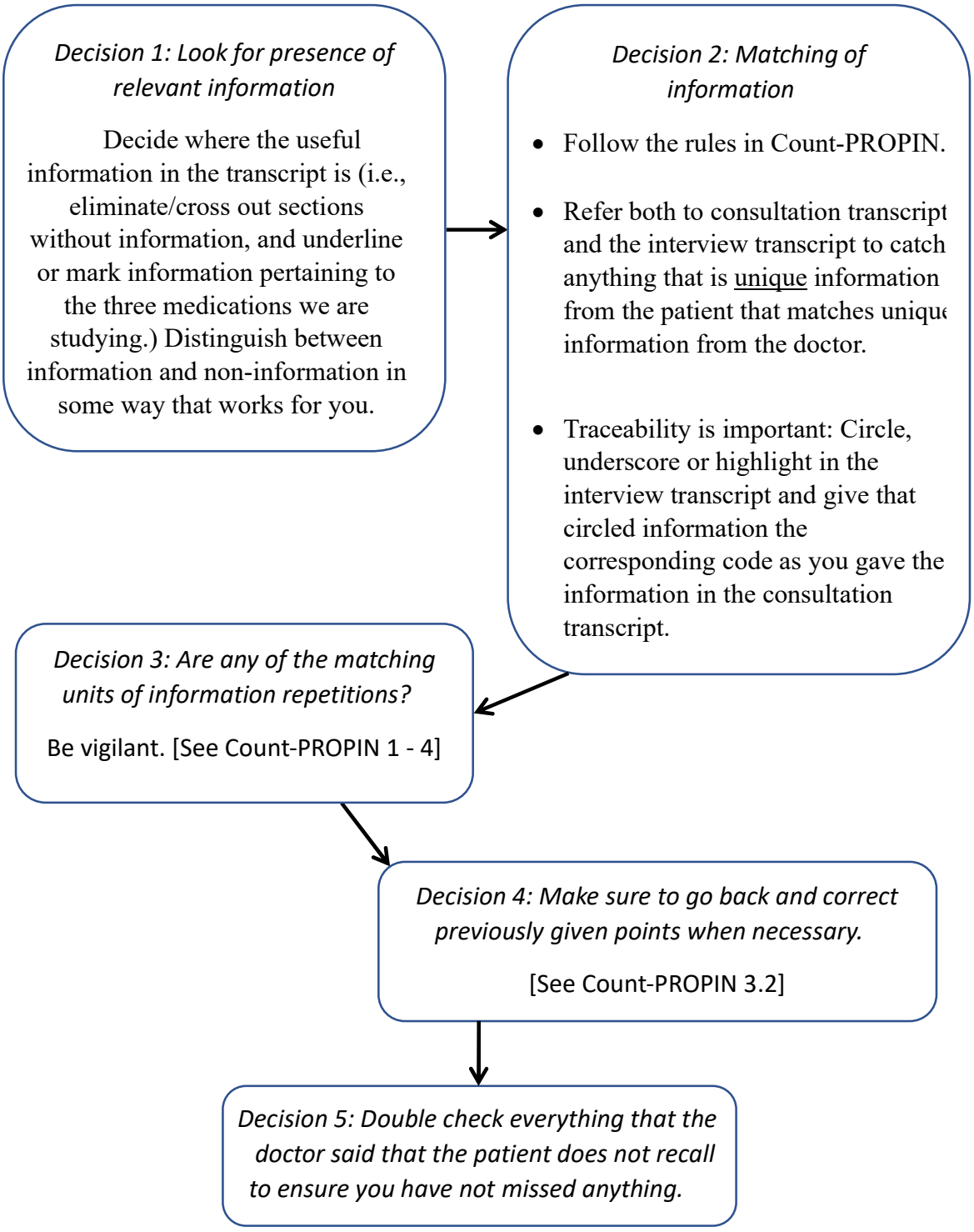
→ Gilenya [a] – option (participant) 1p
→ Is a pill [b] – administration manner (quality) 1p
→ Which you take daily [c]- administration frequency (event) 1p

= Count 3 units of information 3p

3. Practical advice for using Count-PROPIN

The coder is advised to keep the consultation transcript with his or her notes present while going through the interview transcript. When the patient manages to recall any of the units of information given by the physician, this should be marked; e.g. with which line in the consultation transcript the unit of information was given in and marked with a),b) or c) to keep track of which unit of information in the sentence they stem from.

Decision Tree for analysis of the information recalled by the patient.



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Appendix C

Forespørsel om deltakelse i forskningsprosjektet

"Pasientmedvirkning ved multippel sklerose-behandling"

Bakgrunn og hensikt
Vi studerer hvordan multippel sklerose-pasienter informeres og medvirker i beslutninger om behandling, og vil også teste ut nye måter å gjøre dette på. Formålet er finne frem til bedre måter å gjøre det på enn det som skjer i dag. Akershus universitetssykehus er forskningsansvarlig for studien.

Hva innebærer studien?
Studien har to deler, og vi spør deg om du vil være med i studie 2.
I studie 2 sammenlikner vi en ny måte å gi informasjon på med det som er vanlig i dag. Informasjonen vil handle om noe som er viktig for MS-pasienter, men som ikke gjelder deg personlig. Samtalen vil bli filmet. Du besvarer spørreskjemaer og gjennomgår etterpå et intervju med en forsker. Denne samtalen vil også bli filmet.

Mulige fordeler og ulemper
Du har ikke fordeler av å delta i studien, bortsett fra at du kanskje vil vite noe mer enn før om sykdommen og behandling etter å ha vært med i denne studien. Ulempen er at vi etterpå oppbevarer videoklipp av din samtale med legen og intervjuet med forskeren. Disse vil være tilgjengelig for forskere tilknyttet Forskningssenteret ved Akershus Universitetssykehus. Det er også en ulempe at dette tar tid for deg. Vi dekker reiseutgifter og ev. tapt arbeidsfortjeneste hvis deltakelsen må skje i din normale arbeidstid.

Hva skjer med informasjonen om deg?
Informasjonen vi har om deg (fra journal, videoen, intervjuet og spørreskjemaene) blir lagret forskriftsmessig ved Akershus universitetssykehus. Du vil være gjenkjennelig på videopptakene. Disse vil derfor oppbevares slik at kun forskerne i denne studien kan se og lytte til dem. Helsepersonellet som behandler deg har ikke tilgang.
Informasjon som hentes ut fra videopptakene og spørreskjemaene (som for eksempel utskrift av samtale) vil bli lagret uten navn, fødselsnummer eller andre opplysninger som kan identifisere deg. Det er kun forskere knyttet til dette og senere prosjekter som har adgang til navnelisten som knytter deg til dataene. Navneliste må vi ha for å ha mulighet til å slette informasjon om riktig person dersom du skulle ønske dette senere.
Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Frivillig deltakelse
Det er frivillig å delta i studien. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Hvis du ikke ønsker å delta, vil dette ikke få konsekvenser for din videre behandling. Du kan også senere når som helst og uten å oppgi noen grunn trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte overlege Trygve Holmøy, Nevroklinikken, Ahus – telefon 02900.

Mer informasjon om studien finnes i kapittel *A* – *utdypende forklaring av hva studien innebærer.* **Mer informasjon om personvern finnes i kapittel B** – *Personvern, biobank, økonomi og forsikring.*
Samtykkeerklæring følger etter kapittel B.[Pasientmedvirkning ved MS-behandling]

Kapittel A - utdypende forklaring av hva studien innebærer

Studie 2
Bakgrunnen for studien er at pasienter ofte synes det er vanskelig å huske all informasjonen de får av leger. I tillegg vet vi at pasienter med MS ofte står overfor spesielt komplisert informasjon og vanskelige valg når det gjelder behandling.
I studie 2 vil vi sammenlikne den vanlige måten å gi informasjon om ulike behandlinger med en ny måte å gjøre det på. Det vil være tilfeldig hvem som får informasjon på vanlig måte og på den nye måten.

Det er viktig at pasientene som er med forstår hvordan det er å ha multippel sklerose, derfor har vi spurt deg om å være med på dette. I denne studien vil du bli gitt informasjon vedrørende et vanskelig behandlingsvalg som ikke handler om deg personlig eller din reelle sykdomssituasjon. Vi gjør studien fordi vi gjerne vil være sikre på hvilken måte å gi informasjon på som er best før vi bruker metoden til pasienter som står i en reell valgsituasjon.

Vi henter følgende opplysninger fra journalen din: Opplysninger om hvilken type MS du har, alvorlighetsgrad og funksjonsnivå, hvor lenge sykdommen har vart, og tidligere og nåværende behandling.

Denne undersøkelsen finner sted på Akershus universitetssykehus, men ikke der du normalt besøker legen. Du skal møte i det bygget som heter Nye Nord, Inngang 4, i fjerde etasje, rett ved biblioteket (se eget informasjonsark for detaljer).

Kapittel B - Personvern, biobank, økonomi og forsikring

Personvern
Personvernombudet ved Akershus universitetssykehus har godkjent måten vi sikrer dataene på. Sykehusdirektøren er overordnet databehandlingsansvarlig.

Rett til innsyn og sletting av opplysninger om deg
Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede opplysninger, hvis ikke opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Økonomi og Extrastiftelsens rolle
Studien er finansiert gjennom forskningsmidler fra Extrastiftelsen etter anbefaling fra MS-forbundet. Extrastiftelsen har ikke stilt noen krav til forskerne når det gjelder analyser og publisering utover at norske regler og lovverk følges. Forskerne opptrer uavhengig av finansieringskilden.

Informasjon om utfallet av studien
Hvis du deltar i studien, har du rett til å bli informert om resultatene når de kommer. Dette tar ofte minst et par år. [Pasientmedvirkning ved MS-behandling]

Tillegg

Vi vil gjerne ha mulighet til å bruke anonymiserte tekstutskrifter av videosamtalene til undervisning av leger, legestudenter og/eller kommunikasjonsforskere. Kan du tenke deg å bidra til dette?


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NEI Jeg ønsker ikke at noen tekstutskrifter av videosamtaler jeg er med i skal brukes i undervisning.

Vi kunne også tenke oss muligheten for å bruke noen av videoopptakene til å undervise leger, legestudenter og/eller kommunikasjonsforskere. Kan du tenke deg å bidra til dette?


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NEI Jeg ønsker ikke at noe videoopptak med meg skal brukes i undervisning.

Samtykke til deltakelse i studien
Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Jeg tillater at video av legesamtale og intervju med forsker oppbevares slik lov og forskrifter krever til og med 31. august 2028.

(Signert av prosjektdeltaker, dato)

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

Navn på pasienten _____

Deltakernummer i studien: _____

Physician participation information and consent form

Forespørsel om deltakelse i forskningsprosjektet *"Pasientmedvirkning ved multippel sklerose-behandling"*

Bakgrunn og hensikt
Vi studerer hvordan multippel sklerose-pasienter informeres og medvirker i beslutninger om behandling, og vil også teste ut nye måter å gjøre dette på. Formålet er finne frem til bedre måter å gjøre det på enn det som skjer i dag. Akershus universitetssykehus er forskningsansvarlig for studien.

Hva innebærer studien?
Studien har to deler. I studie 1 filmer vi konsultasjoner du har med MS-pasienter, der du diskuterer vanskelige behandlingsvalg. Etter konsultasjonen besvarer du spørreskjemaer og gjennomgår et kort intervju med en forsker som blir oppbevart som lydopptak. I studie 2 sammenlikner vi en ny måte å gi informasjon på med det som er vanlig i dag. Informasjonen vil handle om noe som er viktig for MS-pasienter. Pasienter vil bli randomisert til å møte deg før eller etter du har fått opplæring i en ny måte å gi informasjon på. Samtalene vil bli filmet. Du besvarer spørreskjemaer etterpå. I denne studien står pasientene ikke selv overfor reelle behandlingsvalg, men har MS.

Mulige fordeler og ulemper
Fordelen ved å være med i studien er at du får opplæring i en måte å gi informasjon på som er antatt bedre enn vanlig praksis. Ulempen er at vi etterpå oppbevarer videoopptak av dine pasientsamtaler og lydopptak av intervjuer med forskeren. Disse vil være tilgjengelig for forskere i studien. Det er også en ulempe at dette tar tid for deg (ca 15 min ekstra per pasient i studie 1, max. 60 min per pasient i studie 2). Nevroklinikken godtar at prosjektdeltakelsen inngår i arbeidstiden.

Hva skjer med informasjonen om deg?
Informasjonen vi har om deg (fra videoopptak, lydopptak og spørreskjema) blir lagret forskriftsmessig ved Universitetet i Oslo. Du vil være gjenkjennelig på videoer og lydopptak. Disse vil derfor oppbevares slik at kun forskerne i denne studien kan se og lytte til dem.
Informasjon som hentes ut fra videoopptak, lydopptaket og spørreskjema (som for eksempel utskrift av samtale) vil bli lagret uten navn, fødselsnummer eller andre opplysninger som kan identifisere deg. Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Navneliste må vi ha for å ha mulighet til å slette informasjon om riktig person dersom du skulle ønske dette senere.
Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Frivillig deltakelse Det er frivillig å delta i studien. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Hvis du ikke ønsker å delta, vil dette ikke få konsekvenser for deg. Du kan også senere når som helst og uten å oppgi noen grunn trekke tilbake ditt samtykke. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte prosjektleder Pål Gulbrandsen – telefon 95827288.

Mer informasjon om studien finnes i kapittel *A* – *utdypende forklaring av hva studien innebærer.*
Mer informasjon om personvern finnes i kapittel B – *Personvern, biobank, økonomi og forsikring.*
Samtykkeerklæring følger etter kapittel B.[Pasientmedvirkning ved MS-behandling]

Kapittel A - utdypende forklaring av hva studien innebærer

Formålet med studie 1 er å danne seg et bilde av hvordan kompliserte behandlingsvalg diskuteres i dagens praksis. Vi trenger derfor deltakelse fra flere leger, og gjerne mer enn én konsultasjon per lege for å få et begrep om hvordan variasjon i praksis er knyttet til lege og pasient. Din personlige måte å gjøre dette på gjøres ikke til gjenstand for vurdering. Du får selv etter konsultasjonen mulighet til å gi uttrykk for utfordringer i konsultasjonen

og egne vurderinger og prioriteringer. Pasienten intervjues også. Opptakene av konsultasjonen vil finne sted på rom 67 på nevr. poliklinikk.
Resultatene i denne studien vil benyttes i detaljplanleggingen av studie 2.

Formålet med studie 2 er å studere effekten av en ny måte å gi informasjon på. I løpet av studien vil du bli kurset i denne metoden. Du vil ha én pasientsamtale før kurset og én etterpå. Samtalene gjennomføres som vanlige konsultasjoner. Pasientene har MS, men som deltagere i studien vil de få utdelt den kasuistikken de skal forholde seg til. MS-pasientene skal altså behandles som om de står overfor et reelt valg, noe de imidlertid ikke gjør i virkeligheten. Formålet med studien er å se opm pasientene får med seg mer informasjon etter at legen har blitt kurset i en ny måte å informere på. Også her ber vi deg fylle ut spørreskjemaer etterpå. Denne undersøkelsen finner sted i kommunikasjonslaboratoriet i Nye Nord, Inngang 4, i fjerde etasje.

Kapittel B - Personvern, biobank, økonomi og forsikring

Personvern
Personvernombudet ved Universitetet i Oslo har godkjent måten vi sikrer dataene på.
Universitetet i Oslo ved direktøren er databehandlingsansvarlig.

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Hvis du deltar i studien, har du rett til å bli informert om resultatene når de kommer. Dette tar ofte minst et par år. [Pasientmedvirkning ved MS-behandling]

Samtykke til deltakelse i studien

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Jeg tillater at videoopptak og lydopptak av pasientsamtaler og intervju med forsker oppbevares slik lov og forskrifter krever til og med ti år etter at studien er ferdig.

(Signert av prosjektdeltaker, dato)

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

Navn på legen _____

Deltakernummer i studien: _____

Tillegg

Vi vil gjerne ha mulighet til å bruke anonymiserte tekstutskrifter av videosamtalene til undervisning av leger, legestudenter og/eller kommunikasjonsforskere. Kan du tenke deg å bidra til dette?

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NEI Jeg ønsker ikke at noe videoopptak med meg skal brukes i undervisning.

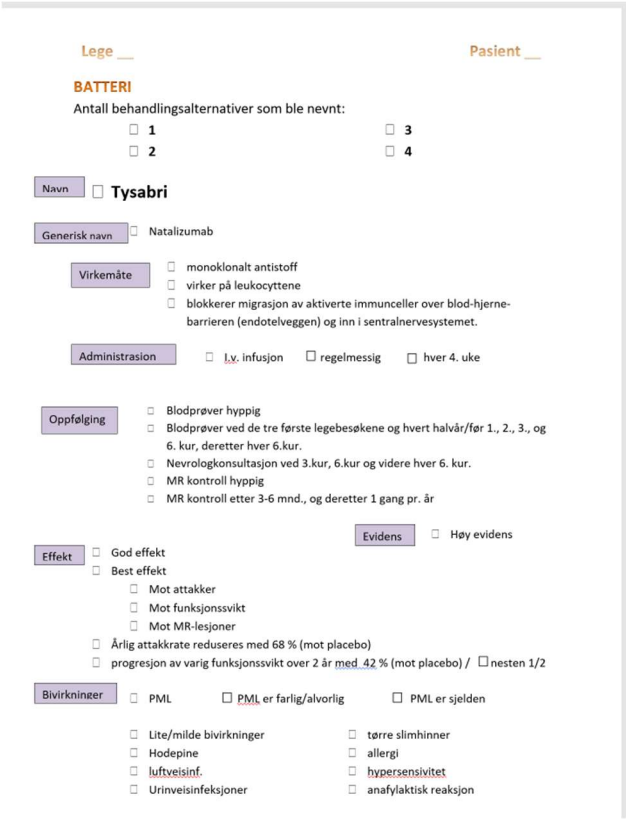
	TECFIDERA Dimetylfumarat
EFFEKT	Årlig attakkrate reduseres med 44-53 vs. placebo.[1] Progresjon av varig funksjonssvikt reduseres med 22-32 % sammenlignet med placebo (høy evidens). 75-94 % færre kontrastoppladende lesjoner på MR vs. placebo. <u>Effekt av Tecfidera når pasienten har hatt 1-2 attakker under behandling:</u> Det er svært vanskelig å si noe sikkert om hvor effektiv videre behandling med dimetylfumarat vil være i denne situasjonen. Det vil være rimelig å anta at sykdommen fremdeles er aktiv, og vil utvikle seg, men umulig å si hvor raskt. I et tiårsperspektiv vil det være sannsynlig at pasienten har en klar progresjon av varig funksjonssvikt.
FARLIGE BIVIRKNINGER	Det er nylig sett et tilfelle av JCV-indusert PML hos en pasient som hadde fått Tecfidera.[2] Fire andre tilfeller er sett hos pasienter som har fått Fumaderm mot psoriasis.[3] Alvorlig lymfopeni tros øke risikoen for PML-utvikling.
Administrasjon	Peroral, 240 mg x 2 daglig
Oppfølging	Jevnlig blodprøvekontroll. . Vaksiner kan være mindre effektive under Tecfidera-behandling. Unngå levende vaksiner.
Bivirkninger	Flushing, kvalme, diaré, magesmerter. Økte levertransaminaser, leukopeni. Tecfidera kan nedsette effekten av p-piller.
Graviditet	Krysser placenta. Få data. Ingen teratotoksisitet i dyrestudier. 38 fødsler i kliniske MS-studier (22 friske barn født, 3 spontanaborter) Skal bare brukes under graviditet hvis strengt nødvendig, og dersom potensiell fordel av behandlingen oppveier potensiell risiko for fosteret.
Amming	Overgang til morsmelk, men i lavere konsentrasjon enn serum. Fordelene av amming for barnet må veies mot fordelene av behandling for moren.
KONTRA-INDIKASJONER	Persistent lymfopeni

	GILENYA Fingolimod
EFFEKT	Årlig attakkrate reduseres med 55 % og progresjon av varig funksjonssvikt over 2 år reduseres med ca. 30 % sammenliknet med placebo (evidens av høy kvalitet). Langtidsdata viser også god effekt og safety (class IV).
FARLIGE BIVIRKNINGER	Det er rapportert enkelttilfeller av følgende sykdommer: · 5 tilfeller av PML. Prevalens 1.7 per 100000 · 2 fatale tilfeller av hemofagocyttisk syndrom. · utvikling til tumefactiv MS etter oppstart med Gilenya · 2 tilfeller med kryptokokk meningoencefalitt under beh. · 1t tilfelle av herpes simplex encefalitt under Gilenyabeh. · ventrikkeltachycardi 3 uker e. oppstart hos en tidligere mitoxantronepasient · tilfeller av lymfom og basalcelle carcinom under Gilenyabeh.
Administrasjon **Rebound** **Oppfølging** **Bivirkninger** **Graviditet** **Amming**	1 kapsel daglig. Pas. overvåkes i 6 timer ved første oppstart NB. Hvis pas. har glemt tabletten, tas aldri dobbel dose. Har pas. glemt tabletten i mer enn 2 uker skal lege alltid kontaktes. Seponering av behandlingen kan hos noen få gi en rebound effekt, hvor sykdommen kommer tilbake i form av mer alvorlige attakker enn før behandlingsstart. Frekvensen er ennå ukjent, men synes å være klinisk relevant.[4] Øyeus. og hematologi 3 måneder etter oppstart. Leverprøver skal kontrolleres måned 1,3,6,9,12 hos fastlege. Vaksiner kan være mindre effektive under og 2 måneder etter beh. Unngå levende vaksiner. Vanlige: Hodepine, influensa, diaré, ryggsmerter, forhøyede leverprøver, lymfopeni (20-30 %). Mulige: Bl.a.: bradykardi, AV – blokk. (NB: se preparatomtale for ytterligere biv.) Bør seponeres senest 10 dager før forsøk på å bli gravid. Teratogent i dyrestudier. Fingolimod går over i morsmelk. Mulig skadelig for barnet.
KONTRA-INDIKASJONER	Kjent immunsviktsykdom, sykdommer assosiert med immunsvikt Økt risiko for opportunistiske infeksjoner. Alvorlig eller aktiv infeksjon Aktiv kreftsykdom (inkl. kutant basalcellekarsinom) Alvorlig nedsatt leverfunksjon Intoleranse/ allergi for fingolimod (Gilenya) Graviditet eller amming. Bruk av klasse Ia eller klasse III antiarytmika Pågående immunmodulerende behandling Ved hjertesykdom, arytmi, forlenget QT-tid, ukontrollert hypertensjon, cerebro-vaskulær sykdom, gjentatte synkoper og alvorlig ubehandlet søvnapnoe bør Gilenya kun vurderes i samråd med kardiolog

	LEMTRADA Alemtuzumab
EFFEKT	Årlig attakkrate reduseres med 49-55 % ; progresjon av varig funksjonssvikt over 2 år reduseres med 30-42 %, og MR-lesjoner med 61-63%, sammenliknet med interferon beta-1a (evidens av høy kvalitet)[5,6.] *(Fase III studier av alle interferon beta preparat har vist god effekt i reduksjon av årlig attakk residiv på ca. 30%–34%)* Effekt vedvarer i lang tid etter at medisinen er ute av kroppen.
FARLIGE BIVIRKNINGER	Autoimmune sykdommer hos ca. 48 %; · immunologisk trombocytopeni (ITP) 3,5 %1 · thyroideasykdommer 41 %7 · hyperthyreoidisme 63 % · hypothyreoidisme 34 %, (kan kreve kirurgi og livslang subst.beh.) · nefritt 0,4 % (oftest ufarlig, dramatisk anti-GBM-sykdom kan forekomme)
Administrasjon	Første syklus/kur: Innleggelse. -En infusjon à 12 mg daglig i 5 dager under 1 måneds dekke av Acyclovir. Andre syklus e.ett år: Innleggelse. -En infusjon à 12 mg daglig i 3 dager under 1 måneds dekke av Acyclovir. (Noen trenger flere sykluser pga. residiv. I en obs.studie trengte 36 % 3 kurer, 8 % 4 kurer og 1 % 5 kurer)
Oppfølging	Månedlig blod/urinprøve i fire år etter siste infusjon pga risiko for nefritt/trombocytopeni. TSH hver 3. måned.
Bivirkninger	Infusjonsrelaterte bivirkninger (inkl. utslett) hos opptil 98 %. Infeksjoner: Reaktivering av HZV og VZV er rapportert To tilfeller av Listeria meningitt i forb. Med kur er rapportert Ett tilfelle av fulminant cerebral nocardiose er rapportert
Graviditet	Ukjent skadepotensiale. Man skal vente 4 måneder etter siste behandlingssyklus før man blir gravid. Obs: Sekundær thyreoideasykdom gir økt risiko for spontanabort og fosterpåvirkning.
Amming	Ukjent skadepotensiale. Mulig skadelig for barnet under og 4 måneder etter behandling.
KONTRA-INDIKASJONER	Kjent immunsvikt Residiverende opportunistiske infeksjoner Hypersensitivitet overfor virkestoffet

	TYSABRI Natalizumab
EFFEKT	Årlig attakkrate reduseres med 68 %.[8] Progresjon av varig funksjonssvikt over 2 år reduseres med 42 % vs. placebo (høy evidens)[8]. Signifikant færre kontrastoppladende lesjoner på MR vs. placebo. NAB-antistoffer reduserer effekten.[1]
FARLIGE BIVIRKNINGER	Progressiv multifokal leukoencefalopati (PML) som kan være fatal eller gi varig nevrologisk skade. Mortalitet blant MS pasienter med PML er 20 %. JCV-antistoff neg: lav risiko (0,09/1000, dvs. 1 per 11 111) JCV antistoff pos: økt risiko med ca. 40 ggr., til 3.9/1000 (eller 1 per 263) Økt risiko ved tidligere immunosuppressiv behandling, og ved behandling med natalizumab i > 25 mnd. Risiko: 11.1/1000 (eller 1 per 90) pasienter. Økt risiko ved høyantistoff-index: Index < 1.5: opptil 1.37/1000 (eller 1 per 730) ved behandling i 4-5 år. Index >1.5 : risiko 10.12/1000 (eller 1 per 99) ved behandling i 4- 5 år. NB: Årlig serokonversjonsrate på 7,1%. Dvs. at i løpet av 4 år blir mer enn 25 % av seronegative pasienter JCV-positive[9]
Administrasjon	300 mg i.v. infusjon hver 4. uke
Oppfølging	Blodprøver før 1., 2., 3., og 6. kur, deretter hver 6.kur. Nevrologkonsultasjon ved 3.kur, 6.kur og videre hver 6. kur. MR kontroll etter 3-6 mnd., og deretter 1 gang pr. år
Rebound	Ved seponering kommer sykdomsaktiviteten tilbake noen måneder senere. Hos ca 20% oppstår reboundfenomen med mer alvorlige attakker enn før behandlingsstart.
Bivirkninger	Generelt godt tolerert. Kan gi hodepine, luft- og urinveisinfeksjoner, tørre slimhinner. Hypersensitivitet og anafylaktoide reaksjoner
Graviditet	Få data, ingen sikker teratogen effekt. Nyfødte av mødre eksponert for natalizumab i 3. trimester bør overvåkes for trombocytopeni og anemi
Amming	Natalizumab er sannsynligvis trygt under amming.
KONTRA-INDIKASJONER	Immunsvikt, immunsykdom, pågående immunmodulerende behandling, PML, infeksjon, kreft, hypersensitivitet mot virkestoffet.

Check list for use during consultation observation and following interview.



Lege __ Pasient __

BATTERI

Antall behandlingsalternativer som ble nevnt:

☐ 1 ☐ 3
☐ 2 ☐ 4

Navn ☐ **Tysabri**

Generisk navn ☐ Natalizumab

Virkemåte
- ☐ monoklonalt antistoff
- ☐ virker på leukocyttene
- ☐ blokkerer migrasjon av aktiverte immunceller over blod-hjerne-barrieren (endotelveggen) og inn i sentralnervesystemet.

Administrasion ☐ I.v. infusjon ☐ regelmessig ☐ hver 4. uke

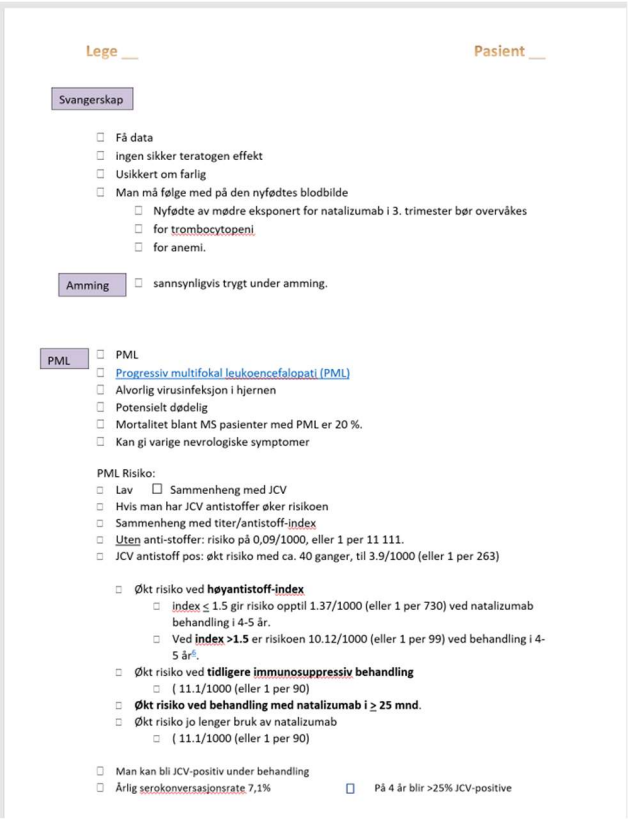
Oppfølging
- ☐ Blodprøver hyppig
- ☐ Blodprøver ved de tre første legebesøkene og hvert halvår/før 1., 2., 3., og 6. kur, deretter hver 6.kur.
- ☐ Nevrologkonsultasjon ved 3.kur, 6.kur og videre hver 6. kur.
- ☐ MR kontroll hyppig
- ☐ MR kontroll etter 3-6 mnd., og deretter 1 gang pr. år

Evidens ☐ Høy evidens

Effekt
- ☐ God effekt
- ☐ Best effekt
  - ☐ Mot attakker
  - ☐ Mot funksjonssvikt
  - ☐ Mot MR-lesjoner
- ☐ Årlig attakkrate reduseres med 68 % (mot placebo)
- ☐ progresjon av varig funksjonssvikt over 2 år med 42 % (mot placebo) / ☐ nesten 1/2

Bivirkninger ☐ PML ☐ PML er farlig/alvorlig ☐ PML er sjelden

- ☐ Lite/milde bivirkninger
- ☐ Hodepine
- ☐ luftveisinf.
- ☐ Urinveisinfeksjoner
- ☐ tørre slimhinner
- ☐ allergi
- ☐ hypersensivitet
- ☐ anafylaktisk reaksjon



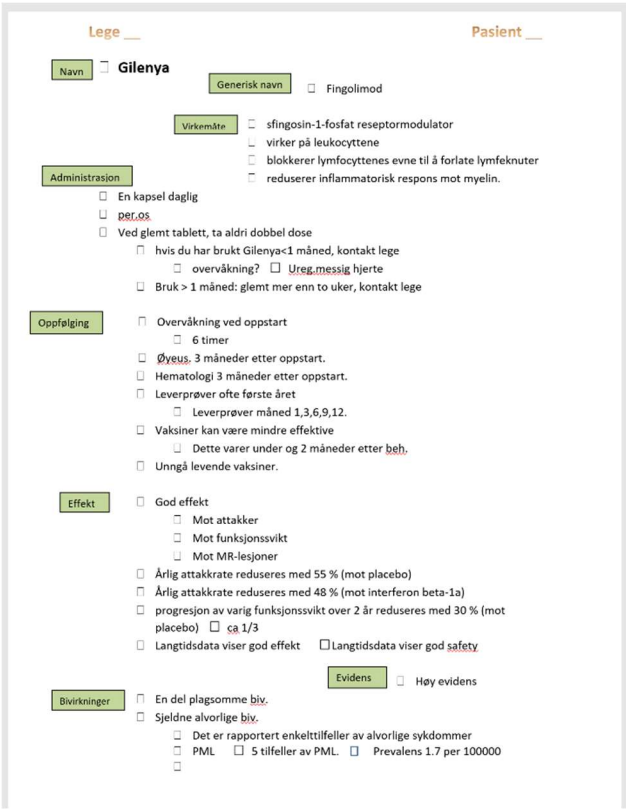
Lege __ Pasient __

Svangerskap
- ☐ Få data
- ☐ ingen sikker teratogen effekt
- ☐ Usikkert om farlig
- ☐ Man må følge med på den nyfødtes blodbilde
  - ☐ Nyfødte av mødre eksponert for natalizumab i 3. trimester bør overvåkes
  - ☐ for trombocytopeni
  - ☐ for anemi.

Amming ☐ sannsynligvis trygt under amming.

PML
- ☐ PML
- ☐ Progressiv multifokal leukoencefalopati (PML)
- ☐ Alvorlig virusinfeksjon i hjernen
- ☐ Potensielt dødelig
- ☐ Mortalitet blant MS pasienter med PML er 20 %.
- ☐ Kan gi varige nevrologiske symptomer

PML Risiko:
- ☐ Lav ☐ Sammenheng med JCV
- ☐ Hvis man har JCV antistoffer øker risikoen
- ☐ Sammenheng med titer/antistoff-index
- ☐ Uten anti-stoffer: risiko på 0,09/1000, eller 1 per 11 111.
- ☐ JCV antistoff pos: økt risiko med ca. 40 ganger, til 3.9/1000 (eller 1 per 263)
  - ☐ Økt risiko ved **høyantistoff-index**
    - ☐ index ≤ 1.5 gir risiko opptil 1.37/1000 (eller 1 per 730) ved natalizumab behandling i 4-5 år.
    - ☐ Ved **index >1.5** er risikoen 10.12/1000 (eller 1 per 99) ved behandling i 4-5 år[6].
  - ☐ Økt risiko ved **tidligere immunosuppressiv behandling**
    - ☐ (11.1/1000 (eller 1 per 90)
  - ☐ **Økt risiko ved behandling med natalizumab i ≥ 25 mnd.**
  - ☐ Økt risiko jo lenger bruk av natalizumab
    - ☐ (11.1/1000 (eller 1 per 90)
- ☐ Man kan bli JCV-positiv under behandling
- ☐ Årlig serokonversasjonsrate 7,1% ☐ På 4 år blir >25% JCV-positive



Lege __ Pasient __

Navn ☐ **Gilenya**

Generisk navn ☐ Fingolimod

Virkemåte
- ☐ sfingosin-1-fosfat reseptormodulator
- ☐ virker på leukocyttene
- ☐ blokkerer lymfocyttenes evne til å forlate lymfeknuter
- ☐ reduserer inflammatorisk respons mot myelin.

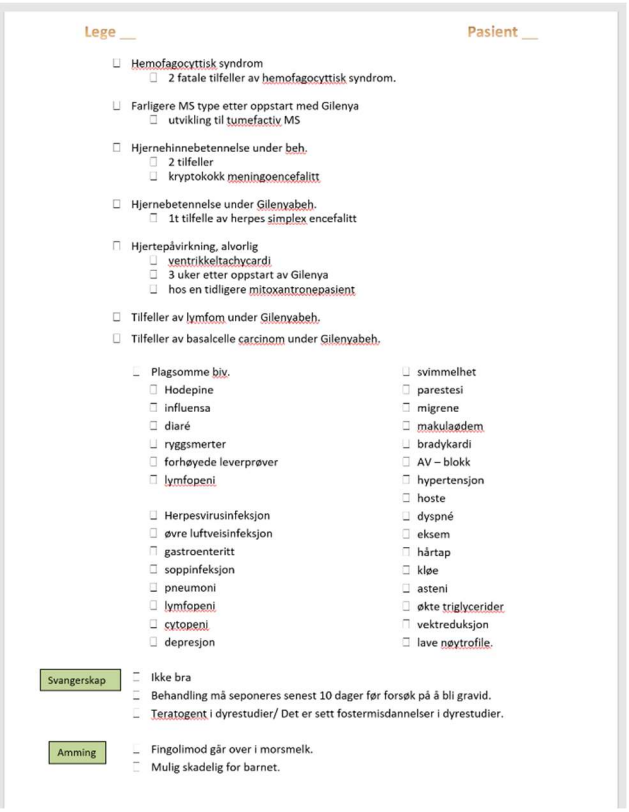
Administrasjon
- ☐ En kapsel daglig
- ☐ per.os
- ☐ Ved glemt tablett, ta aldri dobbel dose
  - ☐ hvis du har brukt Gilenya<1 måned, kontakt lege
    - ☐ overvåkning? ☐ Ureg.messig hjerte
  - ☐ Bruk > 1 måned: glemt mer enn to uker, kontakt lege

Oppfølging
- ☐ Overvåkning ved oppstart
  - ☐ 6 timer
- ☐ Øyeus. 3 måneder etter oppstart.
- ☐ Hematologi 3 måneder etter oppstart.
- ☐ Leverprøver ofte første året
  - ☐ Leverprøver måned 1,3,6,9,12.
- ☐ Vaksiner kan være mindre effektive
  - ☐ Dette varer under og 2 måneder etter beh.
- ☐ Unngå levende vaksiner.

Effekt
- ☐ God effekt
  - ☐ Mot attakker
  - ☐ Mot funksjonssvikt
  - ☐ Mot MR-lesjoner
- ☐ Årlig attakkrate reduseres med 55 % (mot placebo)
- ☐ Årlig attakkrate reduseres med 48 % (mot interferon beta-1a)
- ☐ progresjon av varig funksjonssvikt over 2 år reduseres med 30 % (mot placebo) ☐ ca 1/3
- ☐ Langtidsdata viser god effekt ☐ Langtidsdata viser god safety

Evidens ☐ Høy evidens

Bivirkninger
- ☐ En del plagsomme biv.
- ☐ Sjeldne alvorlige biv.
  - ☐ Det er rapportert enkelttilfeller av alvorlige sykdommer
  - ☐ PML ☐ 5 tilfeller av PML. ☐ Prevalens 1.7 per 100000
  - ☐



Lege __ Pasient __

- ☐ Hemofagocyttisk syndrom
  - ☐ 2 fatale tilfeller av hemofagocyttisk syndrom.
- ☐ Farligere MS type etter oppstart med Gilenya
  - ☐ utvikling til tumefactiv MS
- ☐ Hjernehinnebetennelse under beh.
  - ☐ 2 tilfeller
  - ☐ kryptokokk meningoencefalitt
- ☐ Hjernebetennelse under Gilenyabeh.
  - ☐ 1t tilfelle av herpes simplex encefalitt
- ☐ Hjertepåvirkning, alvorlig
  - ☐ ventrikkeltachycardi
  - ☐ 3 uker etter oppstart av Gilenya
  - ☐ hos en tidligere mitoxantronepasient
- ☐ Tilfeller av lymfom under Gilenyabeh.
- ☐ Tilfeller av basalcelle carcinom under Gilenyabeh.

- ☐ Plagsomme biv.
- ☐ Hodepine
- ☐ influensa
- ☐ diaré
- ☐ ryggsmerter
- ☐ forhøyede leverprøver
- ☐ lymfopeni
- ☐ Herpesvirusinfeksjon
- ☐ øvre luftveisinfeksjon
- ☐ gastroenteritt
- ☐ soppinfeksjon
- ☐ pneumoni
- ☐ lymfopeni
- ☐ cytopeni
- ☐ depresjon
- ☐ svimmelhet
- ☐ parestesi
- ☐ migrene
- ☐ makulaødem
- ☐ bradykardi
- ☐ AV – blokk
- ☐ hypertensjon
- ☐ hoste
- ☐ dyspné
- ☐ eksem
- ☐ hårtap
- ☐ kløe
- ☐ asteni
- ☐ økte triglycerider
- ☐ vektreduksjon
- ☐ lave nøytrofile.

Svangerskap
- ☐ Ikke bra
- ☐ Behandling må seponeres senest 10 dager før forsøk på å bli gravid.
- ☐ Teratogent i dyrestudier/ Det er sett fostermisdannelser i dyrestudier.

Amming
- ☐ Fingolimod går over i morsmelk.
- ☐ Mulig skadelig for barnet.

Lege __ Pasient __

Navn **Lemtrada**

Generisk navn Alemtuzumab

Virkemåte
- monoklonalt antistoff
  - mot lymfocytter
    - CD52 på T-lymfocytter og B-lymfocytter.
    - Gir uttømming og repopularisering av lymfocytter
    - reduserer inflammatorisk respons ved MS.

Administrasjon
- Infusjon Innleggelse
- Første syklus/kur: 12 mg daglig i 5 dager
  - 1 måneds dekke av Acyklovir/antiviral medisin
- Tre sykler
  - Andre syklus etter ett år: En infusjon a 12 mg daglig i 3 dager
    - Samme prosedyrer som ved første kur.
  - Flere sykluser (med ett års mellomrom)?
  - Noen trenger ytterligere sykluser pga attakk residiv.
  - I en obs.studie trengte 36 % 3 kurer, 8 % 4 kurer og 1 % 5 kurer

Oppfølging
- månedlig blod/urinprøve i fire år etter siste infusjon
  - pga risiko for nefritt/trombocytopeni.
- TSH hver 3. måned.

Evidens Høy evidens

Effekt
- God effekt
  - Mot attakker
  - Mot funksjonssvikt
  - Mot MR-lesjoner → ca 1/2
- Årlig attakkrate reduseres med 55 - 49 % sml. med interferon beta-1a
- progresjon av varig funksjonssvikt reduseres over 2 år med 42 % sammenliknet med interferon beta-1a
- Beskytter i lang tid

Bivirkninger
- Autoimmune sykdommer ca. 48 %
- Stoffskifteproblemer thyreoidea /skjoldbruskkjertel 41 %
  - Kan håndteres
  - Hyperthyreoidisme 63 %
    - sterk svetting
    - uforklarlig vekttap
    - hovne øyne
    - nervøsitet
    - raske hjerteslag

Lege __ Pasient __

- hypothyreoidisme 34 % Kan behandles Påvirke trening
  - uforklarlig vektøkning
  - frysing
  - tretthet
  - nyoppstått forstoppelse
- trombocytopenisk purpura (ITP) 3,5 %
  - Blåmerker
  - Utslett
- nefritt 0,4 %
  - ofte ufarlig glomerulonefritt
  - dramatisk anti-GBM nefritt kan forekomme.
    - Tegn på nefritt:
      - Blod i urin
      - Hevelse i ben
      - opphosting av blod

Bivirkninger: når?
- De fleste bivirkninger oppstår innen 2 år
- Økt risiko for autoimmune sykdommer
  - ved røyking
  - ved autoimmune sykdommer i familien
- Infusjonsrelaterte bivirkninger (inkl utslett) forekommer
  - hos opptil 98 %
- Infeksjoner:
  - Enkeltepisoder av infeksjoner er rapportert.
  - Reaktivering av herpes zoster er rapportert.
  - Reaktivering av varicella zoster er rapportert.
  - To tilfeller av Listeria meningitt i forbindelse med kur er rapportert
- Det er ikke observert alvorlige opportunistiske infeksjoner.

Svangerskap
- Bra hvis ferdig med kuren
- Ukjent skadepotensiale
- 4 måneder etter siste behandlingssyklus kan man bli gravid.
- Obs: Sekundær thyreoideasykdom medfører økt risiko for spontanabort og fosterpåvirkning

Amming
- Ukjent skadepotensiale.
- Mulig skadelig for barnet under og 4 måneder etter behandling.

Lege __ Pasient __

Navn **Tecfidera**

Generisk navn Dimetylfumarat

Virkemåte
- immunmodulerende
- anti-inflammatoriske egenskaper

Administrasjon
- peroral, 240 mg x 2 daglig

Oppfølging
- Blodprøver jevnlig
- Vaksiner kan være mindre effektive under Tecfidera-behandling.
- Unngå levende vaksiner.

Effekt
- God effekt
  - Mot attakker
  - Mot funksjonssvikt
  - Mot MR-lesjoner

Evidens Høy evidens

- Årlig attakkrate reduseres med 44-53 % (mot placebo)
- progresjon av varig funksjonssvikt reduseres med 22-32 % (mot placebo)
- Å fortsette med Tecfidera *etter* progresjon: usikker effekt.
- Å fortsette med T. *etter* progresjon: sannsynlig funksjonssvikt over tid

Bivirkninger
- Enkelttilfeller av PML
- Sett ETT tilfelle av JCV-indusert PML hos en pasient som fått dimetylfumarat.
- Fire pasienter med salvebehandling (Fumaderm mot psoriasis) har fått PML
- Alvorlig lymfopeni tros øke risikoen for PML-utvikling.
  - PML er farlig/alvorlig

- Mye bivirkninger
- Vanlig med fordøyelses/GI-plager
- Økte levertransaminaser, leukopeni.
- Kan nedsette effekten av p-piller.
- Flushing
- Kvalme
- Diaré
- Magesmerter.

Svangerskap
- Krysser placenta.
- Få data
- Ingen teratotoksisitet i dyrestudier.
- 38 fødsler i kliniske MS-studier
- 22 friske barn født, 3 spontanaborter
- Skal bare brukes under graviditet hvis strengt nødvendig, og dersom potensiell fordel av behandlingen oppveier potensiell risiko for fosteret.

Amming
- Overgang til morsmelk,
  - men i lavere konsentrasjon enn serum.
- Fordelene av amming for barnet og fordelene av behandling for moren bør tas i betraktning.

Informasjon til pasienten før konsultasjonen

1. Du skal være deg selv med de andre sykdommer eller plager du måtte ha, og dine egne erfaringer og kunnskap om MS i dette møtet med legen, men det handler ikke om din egen MS-sykdom og gjelder ikke deg nå i virkeligheten. Det betyr at du må forestille deg at du er i en annen situasjon enn du faktisk er. Dette er de tingene vi ber deg forestille deg:
    a. Du har hatt MS-diagnosen i mer enn ett år, men symptomer lenger enn det.
    b. Du bruker en medisin mot MS i dag som heter Tecfidera.
    c. Nå har du hatt flere nye attakker, et i februar og et i april. Du har fått dårligere funksjonsnivå.
    d. Du har nylig tatt MR-bilder av hodet som du skal få svar på.
    e. Du har nylig tatt en blodprøve du ikke har fått svar på.

2. Legen har kalt deg inn til en time for å informere om svar på både MR og blodprøve, samt diskutere evt. skifte til mer effektive medisiner.

3. Det vil ikke bli noen undersøkelse, og legen vil ikke spørre deg om symptomene dine. Hvis legen «glemmer seg» og begynner å spørre om sykdomsutviklingen din den siste tiden kan du bare si at det har du fått beskjed om ikke å si noe om.

4. Legen snakker for øvrig med deg som om det var en vanlig konsultasjon, og vi tenker at du er som du pleier når du er hos legen. Du kan absolutt stille spørsmål om de medikamentene som er aktuelle å begynne med. Vi stiller ingen krav til deg, det er legens måte å gi informasjon vi studerer.

MS kasus -til legene

I denne konsultasjonen møter du en virkelig pasient som har MS, men som foreløpig ikke har begynt på noen form for annenlinjebehandling. Pasienten er instruert i å bruke sine egne erfaringer, og er seg selv hva gjelder evt. andre sykdommer, livssituasjon eller problemer. MS-sykehistorien nedenfor er fiktiv og **ikke** aktuell for denne pasienten, noe pasienten er fullt klar over. Pasienten har ikke full oversikt over alle detaljene du har fått om sykehistorien, men kjenner til følgende:

a. Han/hun har hatt MS-diagnosen siden 2014, men symptomer lenger enn det.
b. Han/hun bruker i dag en medisin mot MS som heter Tecfidera.
c. Nå har han/hun hatt nye attakker, ett i februar og ett i april, og fått dårligere funksjonsnivå.
d. Det er nylig tatt MR-bilder av hodet som pas ikke har fått svar på.
e. Det er nylig tatt en blodprøve som pas ikke har fått svar på.

Du skal likevel håndtere situasjonen som aktuell for denne pasienten, men ikke gå inn i den fiktive MS-relatert sykehistorien eller undersøke vedkommende.

Oppgaven i denne konsultasjonen er **å informere om prøvesvar og diskutere konsekvensene med pasienten. Dere står overfor et valg mellom å fortsette samme behandling eller velge ett blant flere andre medikamenter.**

Sykehistorien er slik:

Pasienten fikk diagnosen i 2014. Hun hadde noen mulige attakker før diagnostikk, først i 2008, da hun opplevde forbigående lett nedsatt førlighet i venstre arm, som bedret seg i løpet av 3-4 dager. I 2012 snublet hun og falt hun flere ganger da hun jogget om kvelden, men tenkte ikke så mye over det. Januar 2014 fikk hun akutt tåkesyn på høyre øye, og ved nevrologisk undersøkelse fant man også lett ataksi i høyre ben. Hun ble behandlet med Solu-Medrol i.v. med god effekt. Påfølgende utredning med MR cerebrum og cervikalmedulla viste 8 periventrikulære og 7 juxtakortikale lesjoner med høy signalintensitet i hvit substans på T2-vektede sekvenser, og en lesjon som ladet kontrast på T1-vektet sekvens, forenlig med demyeliniserende sykdom. Spinalpunksjon viste oligoklonale IgG bånd i spinalvæsken, lett forhøyet protein, og forhøyet IgG indeks. Hun fikk diagnosen RR-MS.

Primo mars 2014 startet man med Extavia, som anbefalt i LIS-avtalen. EDSS 0. Hun hadde influensalignende symptomer i ett døgn etter injeksjon, samt leddsmerter som vedvarte i 3-4 døgn, og siden hun klinisk var såpass kjekk syntes bivirkningene intolerable for henne. Da hun hadde brukt Extavia i tre måneder valgte man derfor å skifte til Tecfidera (juni 2014). Den første MR-kontrollen ble gjort i september 2014, 6 måneder etter oppstart Extavia. Den viste noe progresjon billedmessig, men man valgte å fortsette med Tecfidera siden hun ikke hadde hatt noen kliniske attakker, og det var usikkert om hun hadde hatt progresjonen før eller etter at hun skiftet til Tecfidera.

Pasienten ble deretter innlagt med MS-attakk i februar 2015; da med nummenhet og dårlig kraft i venstre ben. God effekt av Solu-Medrol, men vedvarende plager med endret sensibilitet. Man valgte den gangen å avvente skifte av medikament. Ny attakk i april 2016 med dårlig balanse og økning av

ataksi høyre ben. Fremdeles dårlig balanse som sekvele etter Solu-Medrol-behandling. Man tok blodprøver inkludert JCV, da man så for seg at hun ville måtte skifte behandling. Hun ble henvist til ny MR-undersøkelse, som hun har tatt. Hun skal få svar på både den og blodprøven i dag.

MR-undersøkelsen viser to nye periventrikulære lesjoner på T2-vektede sekvenser, og én kontrastladende lesjon i cervikalmedulla i nivå med C2/C3. Det er all grunn til å tro at Tecfidera fungerer suboptimalt, og du skal i dag diskutere medikamentomlegging med pasienten.

Problem: pasienten har positiv JCV, index = 0,8.

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RESEARCH ARTICLE Open Access

Development of a measurement system for complex oral information transfer in medical consultations

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Abstract

Background: Information exchange between physician and patient is crucial to achieve patient involvement, shared decision making and treatment adherence. No reliable method exists for measuring how much information physicians provide in a complex, unscripted medical conversation, nor how much of this information patients recall. This study aims to fill this gap by developing a measurement system designed to compare complex orally provided information to patient recall.

Methods: The development of the complex information transfer measurement system required nine methodological steps. Core activities were data collection, definition of information units and the first draft of a codebook, refinement through independent coding and consensus, and reliability testing. Videotapes of physician-patient consultations based on a standardized scenario and post-consultation interviews with patients constituted the data. The codebook was developed from verbatim transcriptions of the videotapes. Inter-rater reliability was calculated using a random selection of 10% of the statements in the transcriptions.

Results: Thirtyfour transcriptions of visits and interviews were collected. We developed a set of rules for defining a single unit of information, defined detailed criteria for exclusion and inclusion of relevant units of information, and outlined systematic counting procedures. In the refinement phase, we established a system for comparing the information provided by the physician with what the patient recalled. While linguistic and conceptual issues arose during the process, coders still achieved good inter-rater reliability, with intra-class correlation for patient recall: 0.723, and for doctors: 0.761. A full codebook is available as an appendix.

Conclusions: A measurement system specifically aimed at quantifying complex unscripted information exchange may be a useful addition to the tools for evaluating the results of health communication training and randomized controlled trials.

Keywords: Patient recall, Medical information, Measurement system, Physician-patient communication, Quantifying information, Information exchange, Shared decision-making, Multiple sclerosis, Escalation treatment, Unit of information

Background

A key element of health care is for physicians to convey information about treatment choices in a way that patients can understand and later recall it. The importance of such information transfer can hardly be exaggerated, as it represents the condition sine qua non for success of care delivery [1]. Over the recent years, information exchange between physician and patient has become more complex, making methodological advances in understanding this issue not only relevant but also particularly challenging. Specifically, less paternalism, more transparency, and a higher degree of patient involvement in decisions are recommended [2–5].

Physicians today need to convey multiple, individualized information about uncertainty concerning prognosis, treatment effect, and risk of serious side effects, and at the same time take into account the need for more patient involvement in decision making, which leads to very

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complex information exchange. Health care providers need to adapt and keep up with the developing ethos.

Bridging the knowledge gap between physician and patient is challenging, even with less complex information [6]. In multiple studies, attempts have been made to evaluate patient recall [7–12]. Most of these studies considered less than 15 items of information given [8–10, 13–15]. Still, patients frequently forgot information within a short time span [8–11]. The amount the patients forgot was proportional to the amount presented [11, 14]. Patient recall has been shown to be less than 50% [10, 13].

It is reasonable to suspect that physicians frequently give patients a lot more than 15 items to remember. When too much complex information is presented, patients may become overwhelmed, rendering them less empowered to take part in the decision-making process [16].

As providing complex information is expected of physicians in medical encounters today, physicians require training on how to do it effectively within the demands of everyday practice. Training interventions require evaluation, generating the need to develop a method for measuring what patients have recalled. That is, to evaluate training interventions, we must be able to measure unscripted, complex information uptake reliably, comparing data from discussions during the encounter itself with data from the patients in a recall check.

In the literature, there are several types of tools or coding systems for measuring physician-patient communication. Most of these coding systems involve descriptive categorization. Among these, some split the interaction into different events to be counted [17], others look at who is talking [18], and what topics are being discussed [6, 19]. Linn and colleagues asked observers to mark on a checklist whether a topic and its subcategories were discussed during the consultation, comparing this list to patient answers on a recall questionnaire administered afterwards [12]. Finally, some look for specific phenomena with the aim of describing them [20].

There are also studies creating methods to assess the transfer of information quantitatively. However, most of these studies limited and/or strictly standardized the content of the information provided. Some of these studies departed from the arena of physician-patient consultation, instead imparting information to the patient from a list or an information movie, subsequently recording how much the patient remembered [11, 21–23]. A method made for strictly standardized contents may not be the best one to measure personally tailored complex information given in extemporaneous speech during dialogic interaction.

Furthermore, the definitions of "unit of information" in existing observational coding tools may limit the possibility of capturing complex information transfer. For example, with RIAS, Roter modified Bales' process analysis scheme [24], by defining a unit of information as the smallest discriminable speech segment to which a rater can assign a classification and which expresses or implies a complete thought [25, 26]. Dunn and colleagues narrowed the definition further by defining a unit of information as "a segment of speech from the doctor expressing a single idea concerning medical issues" [27]. However, in complex information transfer there are sometimes speech segments that carry more than one idea, and have overlapping or mutually exclusive elements. There is information expressing insecurity, utterances like "if x, there is y % risk that z will happen", and other types of rich, complex, borderline information-giving sentences. In addition, patients often paraphrase or simplify their recollections. To produce better solutions, we need to apply a complexity lens to our work [28].

Despite the plethora of observational tools for measuring physician-patient communication, there are no tools specifically developed to grasp the nuances of unscripted doctor-patient conversations during which they discuss complicated information. An exception is a recently published coding methodology aimed to measure patients' memory of medical information delivered extemporaneously; this method, however, may not be widely applicable as it was developed on consultations requiring an interpreter. In addition, the authors themselves declared that the recall elicitation component may have been conducted too broadly and inconsistently [29]. Therefore, there is a need for improving existing measurement systems and providing new reliable methods specifically aimed at quantifying complex information giving as well as the patient recall rate in doctor-patient unscripted consultations.

This article reports the development of a complex oral information transfer measurement system involving the following: The definition of a unit of information, measurement of the number of such units regarding a chosen topic orally provided from physician to patient in a complex clinical consultation, and measurement of the number of units of this information that is recalled by the patient.

Methods

The development, refinement and reliability testing of the complex information transfer measurement system involved nine methodological steps: from defining the data needed for building this tool, to collecting it in form of video-recording standardized patient consultations as well as post-consultation interviews, and then to shaping the measurement system based on extensive analysis of the former. Figure 1 is an overview of the methodological steps.

The first step was identifying a clinical situation that would involve a complex exchange of information about

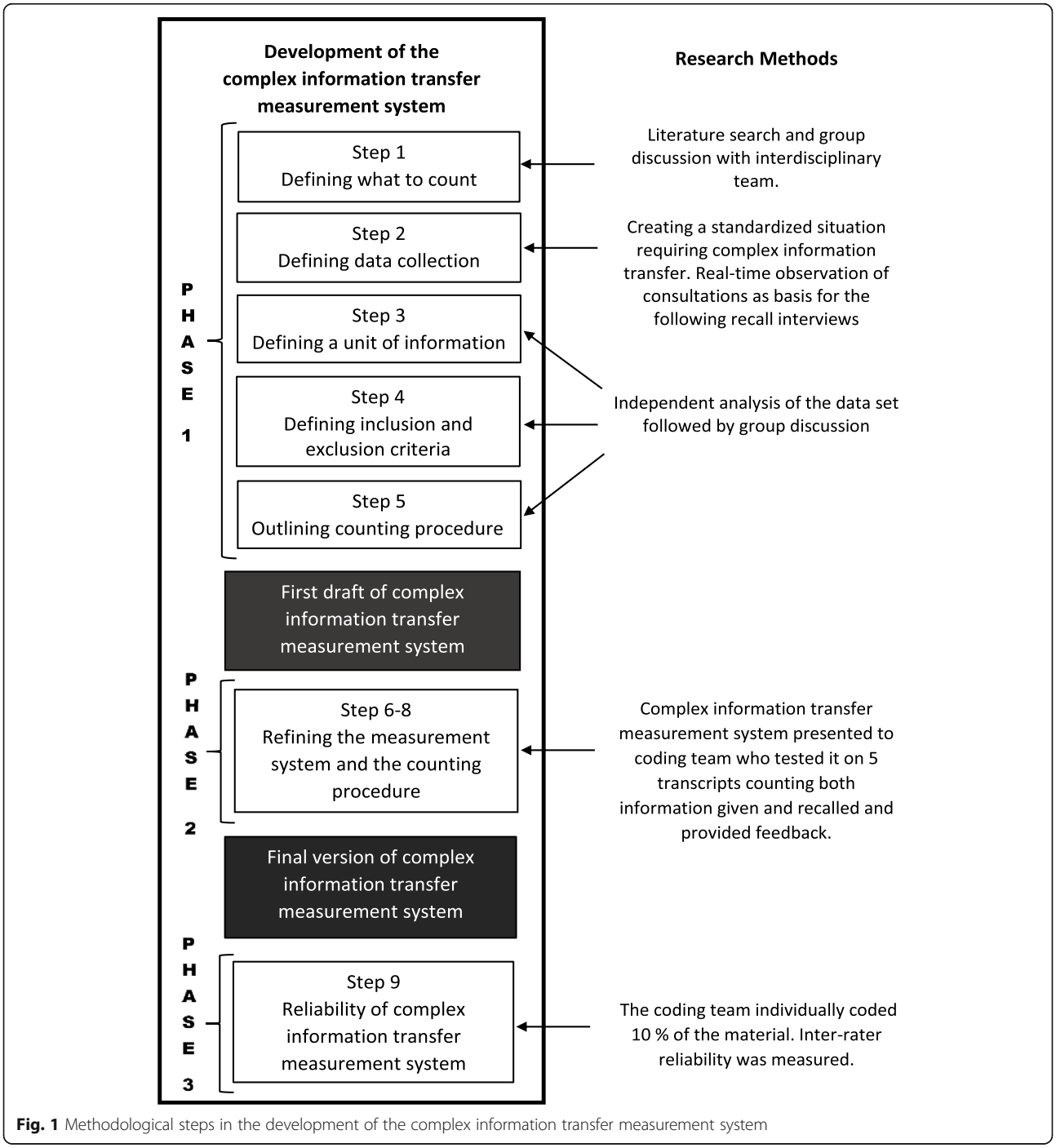

Fig. 1 Methodological steps in the development of the complex information transfer measurement system

medication. We decided to only count information focusing on the three most relevant drug alternatives when initiating second-line MS-treatment. To advise the patient in this choice entails conveying multiple, uncertain, situation-dependent – and thus complex - clinical information. Table 1 summarizes aspects of multiple sclerosis treatment that justify its choice as the clinical scenario for measuring complex information transfer.

The second step was collecting data on the complex information exchange defined in step one. To achieve this, we needed to standardize the clinical setting, by creating a scenario in which initiation of second line treatment had to be discussed. Multiple sclerosis patients, currently on no or first line treatment, were instructed to imagine that they had had two recent attacks and had undergone an MRI-scan and blood tests. Therefore, they were now

Table 1 Aspects of initiating second-line Multiple Sclerosis treatment that makes the information exchange complex

Multiple Sclerosis-related aspects
• Chronic disease
• Unpredictable course
• Potentially physically disabling disease
• Affects cognitive functions
Drug-related aspects
• Available drugs differ in efficacy
• Available drugs differ in risk/adverse effect profile
• Available drugs differ in administration form
• Long-term effects still unknown
Individual-related aspects
• Variability in the response to treatments
• Variability in drug tolerance
• Variability in health literacy
• Variability in understanding of risk

to consult with a neurologist to discuss the results and choice of further treatment. For all the other aspects, the patients were instructed to act as themselves. The same standardized case was given in advance to the neurologists, with specific clinical information and test results. They were also provided with an overview of information on the three most relevant second-line medications, natalizumab, alemtuzumab, and fingolimod, to compensate for differences in their level of experience. Each neurologist saw two patients, and all consultations were videotaped. All participants were recruited from the Neurological Department at Akershus University Hospital.

The interviewer (JN) observed the consultations on screen in real-time, using an observational sheet to register which information each physician conveyed to each patient. The observational sheet was developed to systematically keep track of the complex information conveyed, ensuring a tailored approach to the recall interview. Immediately following the consultation, JN conducted an individual recall interview with the patient. These interviews were also videotaped. The interviews were semi-structured and focused on drug information recall. The first part comprised open questions. Then, based on the notes collected during the observation of the specific consultation, JN narrowed the discussion to more detailed questions that were anchored specifically to the information the doctor had provided during the visit. All video recordings were transcribed verbatim. *The third step* aimed at describing how to identify and quantify unique units of information. We established a coding team of three members with experience from the fields of neurology, public health and communication. Outside the coding team, we had access to psychological and linguistic expertise. The first challenge was to define what a unit of information actually is. We pursued this through group discussion after first familiarizing ourselves individually with the transcripts. Subsequently, the three team members independently analyzed one randomly selected consultation. Then, group discussion revealed disagreements and areas of difficulty in the analysis and in the definition of "unit of information". Discussion continued until they reached a consensus on the definition of unit of information. The same approach was used both in *step four* to reach agreement on inclusion and exclusion criteria for how to treat specific qualities of information (e.g., clarity, perceived medical importance, correctness of utterances) and in *step five* to outline the counting procedure. At that point, we were able to organize our decisions in a first draft of a manual for the reliable quantification of information units that were both conveyed by the doctor and recalled by the patient.

In steps 6–8, we selected five transcriptions, covering variations in the age and experience of the neurologists. Using the manual, all three coders independently counted all units of information delivered by the neurologists. They then analysed the corresponding five transcripts of the post-consultation interviews to count the patients' recollections. Disagreements during the analysis process were resolved through group discussion, thus refining the analysis criteria and enabling the set of rules to cover as many of the problems that could arise as possible. This process was repeated four times, every time leading to revisions of the coding criteria and rules to make the analysis process as practically manageable and as reliable as possible.

In the ninth step, 10% of the information-carrying statements of each transcript was randomly selected and independently coded by the three coding team members, in order to calculate reliability.

Results

The complete measurement system is shown in Additional file 1.

The following sections report the key results of the development process for the complex information transfer measurement system. These are organized following the methodological phases and steps described in the previous section.

First phase: development (steps 1–6)

Data collection (step 1 and 2)

Out of 65 eligible MS-patients diagnosed in 2009–2012 at Akershus University Hospital, 42 agreed to participate. Thirty four finally participated; the others were excluded for practical reasons. Most of the patients were female ($n = 25$; 74%). The patients' mean age was 46, median age 48 (range 29–66 years old).

Seventeen neurologists from the same hospital agreed to participate and to see two patients each. Most of the neurologists were male ($n = 10$; 59%). The neurologists had a mean age of 41, median age 39 (range 29–57 years old), and had between 2 and 29 years of work experience (median = 11, mean = 13).

All 34 consultations and interviews were transcribed. From the consultation transcripts, 1652 statements containing information about our predefined three drug alternatives were identified.

Defining a unit of information (step 3)

Initially, individual preferences regarding how much information to include in one countable unit of information differed considerably among the members of the coding team. To achieve concordance, the consensus was to count as a unit of information the smallest piece of information that still conveyed meaning. For example, in the statement «One option is Tysabri, which you get in a hospital as a monthly infusion. » the smallest possible units of information are:

- One option is Tysabri [a] –*name of medication 1p*
- In a hospital [b] – *administration place 1p*
- infusion [c] – *administration manner 1p*
- monthly [d]- *administration frequency 1p*

Therefore, four units of information are conveyed in this sentence, counting as 4 points for the "doctor's information provision".

Defining inclusion and exclusion criteria (step 4)

Following the development process, we defined a set of inclusion/exclusion criteria around overarching aspects:

(a). The doctor's recommendation: We decided to include doctors' opinions as they are a valuable piece of information for the patient to know (e.g. "If I were you, I would have gone for Lemtrada").
(b). Incorrect information: Sometimes doctors conveyed medically incorrect information or information that was simplified to the point of being incorrect. We decided to include this type of information because the patient would not be able to discern between correct and incorrect information and would still need to process it.
(c). Importance of information: We decided to exclude the possibility of letting certain types of information be worth more points than others as defining "what is important and what is not" would have been not only a highly subjective task but would have implied a paternalistic approach.
(d). General information, in the sense of not specifically pertaining to one or more of the following three second-line multiple sclerosis-medications; natalizumab, alemtuzumab, and fingolimod, was excluded. We only counted information with sufficient contextual anchorage to be assigned to one or more of these specific drugs.
(e). Unclear, ambiguous, incomplete information: Information framed in a way that made it impossible to follow or interpret was excluded from being counted. Examples would be a sentence structure too fractioned to make sense, a double negation, or a lack of intrinsic meaning.

Outlining counting procedures (step 5)

We decided to start by counting the information units given by the doctor, and thereafter count the information units recalled by the patient, the latter to be considered a function of the first, see Fig. 2. This led to the development of a 2-step complex information transfer measurement system consisting of "Counting Complex Orally Provided Information" (Count-COPIN) and "Counting Patient Recall of Orally Provided Information" (Count-PROPIN).

Second phase: refinement

In the three coders' first attempt to apply the draft of the coding system to a subset of data, several aspects were found to require refinement and amelioration. These particularly focused on improving inclusion and exclusion criteria for information recall and optimizing the 2-step procedure of matching doctor's information provision with patient's information recall.

Improving count-COPIN in the complex information transfer measurement system

During the refinement phase, the coders decided not to count utterances with similar meaning twice, even when the doctor rephrased the information. In addition, if the doctor corrected her/himself, the coders decided to count only the last chronological piece of information. While repetitions stating a generalization or simplification were not counted additionally, if the repetition added new information or specified it, the coders agreed to count it additionally. The reasons for not counting repeats that do not add new information was that this would give the doctors a higher count, and thus unfairly reduce the patient recall rate.

Additional necessary precautions to avoid mistakes during counting are presented in the full manual (see Additional file 1).

Improving count-PROPIN in the complex information transfer measurement system

The application of the first version of the measurement system revealed specific situations to discuss (e.g., when

$$\frac{Count-PROPIN\ result}{Count-COPIN\ result} \times 100 = \text{recall percentage}$$

Fig. 2 Calculation of recall percentage

the doctor listed specific points of information, but the patient remembered a general overview). It was decided to count all the mutually exclusive information units given by the doctor, and to give points to the patient for remembering generic overall information as well as specific details. For example, if the doctor gave a list of side effects, each item on the list earned a point. If the patient remembered all of them, each item on the list earned a corresponding point. However, if the patient only remembered that there were lots of side effects, this was awarded one point, as it is a unit of information remembered compared to not remembering anything about side effects. This raised the problem of how to treat, for example, a patient remembering that there were many side effects and then recalling some of the items listed. It was decided that a point would only be awarded for a recalled common denominator as long as not more than two individual items from a list were also remembered.

Furthermore, we decided that the patient would not be awarded points for producing information in the recall interview if:

a. the information was not provided by the doctor during the consultation;
b. the information was attributed to the wrong drug by the patient;
c. the patient was clearly guessing.

An example of this last criterion was a situation in which the patient remembered a specific percentage, but she did not remember the particular context. The patient decided to give the same percentage as her answer to all questions concerning numbers, stating that this strategy would result in a correct answer to at least one question.

Finally, patients sometimes revealed prior knowledge of certain units of information. We decided not to remove points from the patient recall score for this. The reason behind this was the difficulty of verifying and discerning between previous knowledge and knowledge obtained during the consultation. .

Balancing the relation between count-COPIN and count-PROPIN

The material also offered situations in which the information was framed in an "if, then"-statement. Whereas for the physician, we decided to score only the parts of the whole, for patient recall, we decided to score both the parts and the whole (i.e., the relationship between the parts in an "if, then"-construction).

A final challenging aspect during the refinement phase was how to evaluate the patients' understanding of the given information, differentiating between complete or partial understanding and evaluating whether the patient had achieved a good enough understanding. The most endorsed solution was: When in doubt, always err on the side of the patient.

E.g.: Physician: «Tysabri is given in hospital as a monthly infusion. »

[1p-name, 1p-location, 1p-frequency, 1p-admin. = 4p]

Patient recall when questioned on administration manner:

«It was in the blood once a month. »

[1p-frequency, 1p -admin. =2p]

In this case, the patient has already recalled the name of the drug in a previous utterance, so that information unit is already accounted for on the patient's side. "Once a month" is an accurate recall of the doctors' "monthly" =1p. The example is further meant to illustrate that we interpret "in the blood" as a good enough rephrasing of the information unit "infusion" =1p. We will count another point in the patient's favour if she recalls that the drug needs to be administered in the hospital when answering the follow-up probing question.

Third phase: establishing the inter-rater reliability

The intraclass correlation was excellent for COPIN; 0.761 and good for PROPIN; 0.723.

Table 2 shows relevant results when establishing inter-rater reliability.

The ratios of patient recall to information provided for the three coders agreed excellently. We used Bland-Altman plots to identify systematic bias. There was little such bias, which meant we could employ coders interchangeably.

Discussion

This paper reports the development and reliability of a measurement system for complex medical information exchange. Unlike other coding systems that categorize contents [27, 30, 31], or describe interaction and count different types of talk occurring in the medical conversation [26], our measuring system counts the given and recalled units of information, without rating the quality, importance or correctness. This broadens the measurement system and gives it a potential to handle different kinds of complex

Table 2 Interrater reliability of coders, based on 168 randomly selected statements comprising 10% of all statements in the material

	Coder A	Coder B	Coder C
Number of statements coded	168	168	168
Number of COPIN information units identified per statement (average, SD)	2.21 (1.43)	2.61 (1.95)	2.46 (2.05)
Number of PROPIN information units identified per statement (average, SD)	1.02 (1.13)	1.26 (1.34)	1.17 (1.28)
Overall ratio COPIN/PROPIN	0.46	0.48	0.47

information based on the topic under study. Even more, our measurement system overcomes important limitations in the literature as it offers a definition of unit of information that grasps the complexity of information exchange, thus improving methods for collecting patient information recall in unscripted conversations.

The main value of this measurement system is its ability to measure reliably both how many units of information on a pre-defined subject the physician has delivered to the patient, as well as how many of these given units the patient has in fact absorbed and recalled, thus providing a recall rate. It takes into account physicians' repetitions and corrections and patients' paraphrasing, generalizations and simplifications. It measures recall of the "gist" of the information, not only whether the patient is able to reproduce the doctor's words exactly. Furthermore, the measurement system has been developed in a situation resembling real-life, particularly complex for what concerns the information exchanged. Therefore, it presumably fits real-life clinical conversations and the frequent situations during which the information is unsure, complex, individually adapted, and unscripted.

In previous studies on patients' recall of information, recall is based on an often-limited amount of standardized information. Langewitz et al.'s study in 2015 [22] is an example of this, with 28 carefully chosen information units delivered. McCarthy et al. did two trials, delivering respectively 7 and 10 information units [15]. Sandberg did not test patient recall based on a personal medical conversation, but from an instructional video shown to all test subjects [21]. Our method differs from these studies as the amount of information was not limited a priori, nor was its content pre-determined. In a real-life medical consultations, the patient often receives a massive, complex and unselected amount of information, varying in clarity [32] and importance. The sheer amount of this information is likely to affect his or her recall [8, 9]. Hopefully, the information is also tailored to the patients' specific needs, making it personally relevant. When patients expect an issue or a unit of information to have significant consequences for their own lives, they are more likely to become personally involved [33]. Consequently, the information is more deeply processed, and thus better recalled [34]. Our method contains a thorough definition of what a unit of information is, enabling quantification of any information deemed interesting to the research, embedded in complex free speech. This makes the measurement system well equipped for quantifying information in real-life conversations.

Another characteristic of our measurement system is the procedure to collect and evaluate patients' information recall. The human mind can hold so much information, yet we access only a small part at a time. It has been demonstrated that contextual cues affect the ability to retrieve memory items and recall information in different situations [35]. Sandberg et al. compared recognition, free recall and cued recall; all methods used to measure recall in different studies [21]. Their study demonstrated that free recall is poor, but improves as more cues are provided. Performance on the multiple-choice task was better than cued recall performance, which was better than free recall performance [21]. In a recently published method for measuring information transfer, called PICcode [29], a short free recall interview was performed by research assistants who were not aware of the consultation contents. In our study, we wanted the preconditions to be as similar to a natural situation as possible. Therefore, our recall interviews were performed by an interviewer who witnessed the consultations in real time on-screen right ahead of the interview, and therefore was aware of which information had been given. This made it possible to achieve an intimately tailored interview with prompted recall, a technique placed somewhere in between free recall and cued recall. Since the interviewer had a checklist of which topics had been covered in the conversation, she was able to give open prompts, as a means towards making implicit knowledge explicit. With this procedure, the interviewer could ensure that the patients were prompted to search their memory about all topics mentioned by the doctor. Retrieval processes are cue-dependent: what we can and cannot recall at a given point in time is strongly influenced by the cues available to us [35]. If we had asked the patients to write down or just tell to the camera everything they remembered right after the consultation, it is probable that we would have gotten a much lower recall rate. If we had asked a fixed number of predetermined questions, we would not have achieved a reliable recall number for those doctors who had given more details or a higher number of information units. It is reasonable to assume that this tailored interview creates a more valid test of memory as it de

facto works, by jogging the memory about each information unit given by the doctor, and that this would strengthen the reliability of the quantitative relationship between information given and recalled.

We believe that the ability of this measurement system to deal with complexity and provide a summative numerical output of complex information transfer makes it a useful tool for evaluating the impact of communication training interventions designed to improve complex information recall. The measurement system does not provide any kind of qualitative evaluation on the *manner* in which these units of information are delivered, it merely provides a numerical result. It could however be used in combination with other methods of categorization of doctor-patient interaction to see if recall percentage correlates with other communicational aspects. Having videotapes and transcripts available for linguistic analysis has the potential for furthering insight into how the details of communication increase recall rates. As an example, the measurement system could be adapted to investigate how increasing the use of repetitions as an information giving technique would affect patient recall.

The measurement system does not discriminate between information of different degrees of perceived importance, quality or correctness. It could be adapted to evaluating recall rate of all the above-mentioned types of information, but this would require a complementary development of a pre-defined information value scale that would vary with the individual, the chosen subject addressed in the consultation, and the prevailing medical paradigm in the actual practice. Moreover, it does not differentiate nor fully address the complex relationship between recall and understanding, even if it includes rules to credit recall when the information is heavily paraphrased, attempting to catch patient 'gist' understanding as well as more precise recollections. There is a recently published coding scheme that would be better equipped to detect mismatch between the intended meaning of the health care provider and the understanding of the patient [36].

This study has some limitations. First, choosing a standardized situation may have limited the generalizability of our findings to real-life situations.

However, the physicians reported that they found the situation realistic and recognizable. Furthermore, we recruited real MS patients, all in a stage where the fictitious situation was a realistic and foreseeable next stage of their disease. Nearly all patients confirmed that the information provided was relevant to them. Therefore, it is likely that the findings and the measurement system can be generalized and applied to real-life situations.

There is also a possibility of a Hawthorne effect; whether being observed has affected the behaviour of both neurologists and patients [37]. To minimize this possible effect, we used discreet ceiling-based camera equipment, and let the interviewer observe the consultation on-screen in an adjacent room. Neither physicians nor patients seemed to be affected by the cameras.

Another possible limitation of our study is that the reliability of the coding system was calculated on the results of three coders who were all involved in the development of the measurement system. Therefore, the coders were familiar with the problems and discussions preceding the decisions, which could have facilitated the reliability process and results. Further studies should strengthen the assessment of the coding system with external independent coders.

Conclusion

We have developed a reliable method for measuring the information provided and recalled in a complex medical information exchange situation. It was designed for measuring recall in multiple sclerosis patients receiving information from a neurologist about their transition to second line treatment, but the method can potentially be adapted to other healthcare conversations involving complex information delivery. Furthermore, it can represent a reliable and useful tool for measuring the effect of communication training interventions on patient recall. We found high inter-rater reliability in this study. Further studies should follow to determine its reliability and validity in other clinical settings and care situations.

Additional file

Additional file 1: Coding System for Counting Complex Orally Provided Information and Patient Recall (PDF 649 kb)

Abbreviations

Count-COPIN: Counting Complex Orally Provided Information; Count-PROPIN: Counting Patient Recall of Orally Provided Information.; MRI: Magnetic resonance imaging; MS: Multiple Sclerosis; PICcode: Patient-Interpreter- Clinician coding; RIAS: Roter Interaction Analysis System; SD: Standard deviation

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Authors' contributions

Concept and design: PG. Acquisition of data: JN. Analysis or interpretation of data: JN, PG, MN, JM) and JG. Drafting of the manuscript: JN with major contributions from JM. Critical revision of the manuscript for important intellectual content: JM, JG, PG, MN. Obtained funding: PG. All authors have read and approved the final manuscript.

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Availability of data and materials
The data owner is Akershus University Hospital. Requests for anonymized data should be directed to Professor Pål Gulbrandsen.

Ethics approval and consent to participate
The project received ethics approval from the Data Protection Official for Research at Akershus University Hospital. Sensitive data were protected by maintaining the Akershus University Hospital code of conduct in respect of storing data only within specified permitted access drives and using encrypted hardware. Raw data (videotapes) were only available to JN, JG, JM, and PG by administrative permission granted by the CEO of Akershus University Hospital.
All participants were provided with information about the study prior to giving their written consent. Considering that the project involved informing patients about medications and risks related to a later stage of their disease, we involved an ethicist and a patient representative to discuss how to handle the possibility of this causing worry or emotional reactions. As a result, we ensured that medical advice or psychological support was provided in case of need.

Consent for publication
All patients and physicians have given written consent to publication of anonymized content.

Competing interests
The authors declare that they have no competing interests.

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Three strategies when physicians provide complex information in interactions with patients: How to recognize and measure them

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ABSTRACT

Objective: To define and operationalize three taught strategies for providing information in interactions with patients using videos collected in a randomized controlled trial (RCT).
Methods: This was a qualitative exploratory study embedded in a randomized controlled design, using microanalysis of face-to-face dialogue as an inductive video analysis method to operationalize physicians' use of three information-provision strategies. Data were 34 video-recorded simulated (but unscripted) interactions between 17 physicians and 34 multiple sclerosis patients collected before and after a brief course on information provision. We operationalized (1) *mapping the patient's preferences* and (2) *checking the patient's understanding,* and pauses indicative of (3) *portioning information.*
Results: Results are detailed analytical definitions, criteria, and assessable, quantifiable outcomes for each of the three strategies. Patients responded to portioning pauses as expected: whereas 91% of these pauses elicited an immediate patient response, only 23% of non-portioning pauses did so.
Conclusion: Our methods revealed how to define and evaluate information sharing strategies physicians used within the contingencies of clinical interaction.
Practice implications: Findings provide applicable methods to teach, analyze, and evaluate information sharing strategies and indications for further training.

1. Introduction

Since the 1980's, the healthcare delivery paradigm has shifted from physicians being the sole decision-makers to an ideal of the autonomous patient, which has necessitated the evolution of concepts such as informed consent, patient-centered care, and shared-decision making [1–4]. Today, it is a requirement in medical care and research that the patient is well informed [5–7], a standard reflected in legislation [8,9]. Despite these developments, physicians tend to underestimate patients' need for information and overestimate patients' capacity to understand and remember the information provided [10,11]. For example, with medical information provided orally, patients' recall and comprehension is limited to 40–70% [12], a percentage that decreases proportionately as the amount of information provided increases [13,14]. Further, patients misunderstand or incorrectly remember a substantial part of the information physicians provide [13,15,16]. Whereas good information provision practice is positively associated with various objective and subjective patient outcomes [17,18], the pathways connecting specific communication strategies to concrete outcomes are understudied [18,19].

This paper focuses on how to orally provide understandable medical information during interactions with patients, a task physicians face daily [20]. Multiple basic research studies on language use underlines that this process is not simply a matter of transferring information from the physician's mind to the patient's: It is a collaborative, interactive process, during which the two cooperate to accomplish understanding [21].

There have been many attempts to improve the way physicians communicate information orally to their patients [22–24]. In a reflection of collaborative theory, special attention has been placed on how to *tailor* the information to the patient [25]: a key requirement to establish mutual understanding with patients about information that is often complex, uncertain, and technical. Concrete examples of such an effort are strategies aimed at mapping the patients' preferences and needs (and tailoring the information accordingly)

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[26–32], at portioning the information, especially if complex, into more manageable *instalments*, or short noun phrases followed by a pause that invite a listener to respond before the speaker continues [33]. Providing information in instalments allows the patient to contribute [34–37], which can serve the implicit purpose of checking whether the patient is understanding the information provided so far [34,38–40]. These three strategies are among the multiple evidence-based medical communication skills The Calgary–Cambridge guides provide an overview of [41]. These strategies appear straightforward, but within the context of clinical interactions, they require complex collaborative efforts. What these strategies look like in practice (and whether they actually work) has largely eluded research efforts, and, as is often the case of the contents of communication skills training, their promotion has been based mainly on the consensus opinions of experts [23,42–44]. Little research exists regarding how and why these communication strategies support the goal of providing information [45], highlighting the need to strengthen the evidence base linking research, teaching and practice [46].

However, this need faces concrete challenges. First, to define the therapeutic intervention in a communication training module, and assess its outcome, is much more difficult than in a clinical trial [47,48]. There are multiple levels of outcomes to consider, and different models have been created attempting to define them [47–50]. Levinson's model outlined immediate, intermediate and ultimate outcomes, exemplified as improvements in physician behaviour, patient knowledge or satisfaction, and patient health, respectively [49]. Focusing solely on intermediate or ultimate outcomes may obscure important links between interventions, interpersonal, and individual behaviors. Kirkpatrick's four-level model outlined level 1. *reaction*, 2. *learning*, 3. *behaviour* and 4. *results* [50]. Levels 3 (behavior: the trainees' ability to use their newly acquired skills or knowledge in the workplace) and 4 (results: the overall impact of the training) are typically understudied in communication research [51].

Second, when evaluating the skills needed to ensure clear information exchange and understanding, one discovers a limited pool of assessment tools that are shown to be consistent with what is measured, and there are gaps in the methodological quality of many studies [52,53]. For example, various interventions have included mapping patients' preferences and needs as prerequisite for tailoring information but have evaluated this strategy outside the contingencies of the clinical interaction (e.g., with indirect preference elicitation methods, exploring their use with focus groups and semi-structured interviews, or focusing on very specific techniques for mapping) [28].

Third, the evidence base for deriving effective information provision strategies is challenged by difficulties with *reproducibility*, that is, maintaining the integrity of the "dosage" of the communication strategy being taught. Such integrity requires clear and consistent descriptions of the information-giving strategies, so that they can be reproduced in interactions with patients. Such descriptions are still lacking. Recently, a codebook for assessment of communication skills included rating of information-related micro-skills based on audio recording was published [54]. Limitations of that study were that gaze could not be observed and patient recall was not measured.

Qualitative linguistic and conversation analysis methods have provided a deeper understanding of the mechanisms underlying certain communication behaviours in the medical encounter [55]. A clear example is the strategy of portioning information. Linguistic research has shown that speakers naturally decompose information into instalments, inviting addressees to affirm their understanding before going on [33]. When addressees indicate trouble understanding, speakers divide the information into smaller instalments and decrease the length of instalments to seek responses from the addressee more frequently [35,37], thereby enhancing addressee comprehension [36]. These studies justify training physicians to portion complex information into instalments, inviting the patient to confirm understanding or indicate that repair is needed. Dividing information into instalments in order to elicit responses requires precise integration with gaze direction, as speaker gaze has been shown to be associated with addressee responses [56,57].

In the present study, we address the issue of reproducibility by providing clear definitions of the strategies, making it possible to locate when and how often physicians use them and how patients respond.

Using video-recorded data from a previously conducted randomized controlled trial (RCT) [58], we set out to describe how to consistently assess whether the physicians used the communication strategies taught in the course during their interactions with patients. The RCT had evaluated a three-hour training intervention aimed at improving physicians' ability to convey complex information. The course was specifically tailored towards neurologists informing Multiple Sclerosis (MS) patients about treatment escalation options. It contained theoretical instructions and practical training with feedback; according to Kirkpatrick's model, it investigated a level 4 outcome, namely how much information patients recalled [59]. The present study focused on a level 3 outcome (i.e., behavioural), namely, physicians' use of the three information sharing strategies and how to reliably assess them. Key strategies taught during the intervention were:

(1) *Mapping preferences*: Physicians were instructed to ask questions aimed at eliciting the patient's preferences, background and current ideas regarding their disease and treatment. In this way, they could create an opportunity to prioritize and tailor information accordingly.
(2) *Information portioning*: Physicians were taught the importance of pausing after presenting a piece of information, creating meaningful spaces in their information provision sequences in order to provide opportunities for the patient to respond (e.g., confirm understanding or express a need for clarification).
(3) *Checking for understanding*: Physicians were trained to ask the patient to verbalize imparted information back. This strategy provided an opportunity for the physician to evaluate patient understanding.

Each strategy was supported by previous literature and evidence [35,40,60–66]; further, they share similarities in their collaborative nature and complexity in assessment.

We aimed to define and operationalize how physicians accomplished these strategies in interaction, thus providing conceptual knowledge on the observable manifestations of the taught skills and methodological knowledge for assessment. We used this to explore Kirkpatrick level 3 outcomes from an RCT even if this was not its primary outcome.

2. Methods

This was a qualitative exploratory study embedded in a randomized controlled design, using microanalysis of face-to-face dialogue as an inductive video analysis method to operationalize physicians' use of three information-provision strategies.

2.1. Data

This study is based on 34 video-recordings from an RCT conducted between 2016 and 2019, in which MS patients were randomized to meet neurologists either before or after the latter participated in a communication training intervention specifically

Table 1
Participants' characteristics; neurologists (n = 17) and patients (n = 34).

	Neurologists	Patients		
	(n = 17)	*Control (n = 17)*	*Intervention (n = 17)*	*Total*
Female (n, %)	7 (41)	12 (71)	13 (76)	25 (74)
Male (n, %)	10 (59)	5 (29)	4 (24)	9 (26)
Age by first consultation (median, range)	39 (28–57)	48 (29–60)	48 (29–66)	48 (29–66)
Years of clinical experience (median, range)	11 (2–29)			

aimed at conveying complex information about treatment escalation [58].

2.1.1. Participants, setting and procedures

Based on the electronic patient records (EPR) of a Norwegian hospital, 34 patients were recruited to an experimental study where 17 physicians volunteered to participate, see Table 1. Each patient had a diagnosis of relapsing-remitting MS and was currently on none or first-line treatment; none were yet in need of escalation treatment due to increased inflammatory activity or had received information about second-line treatment from a neurologist. The patients were asked to participate by coming in to receive information about choices of escalation therapy imagining that they had experienced symptom aggravation over the last year. Physician-patient interactions were simulated, but unscripted, in that the participants were invited to act as themselves as if they were in this situation [67].

All physicians met with one patient before the course and a different patient afterwards, resulting in 34 videotaped consultations. In the consultation, the neurologists informed the patients about treatment escalation options as if their disease had really gotten worse. The pre-intervention consultations took place between August 9 and September 16, 2016, the intervention in three sessions between September 21–27, 2016, and the post-intervention consultations between October 3 and November 3, 2016. Consultations lasted on average 20 min (range 07:45–28:15 min). The consultations were video-recorded in a physicians' office outfitted with two discrete cameras, simultaneously filming both the patient and the physician face on.

2.2. Data analysis

All videos were transcribed verbatim by the first author and professional transcribers. We used the video and audio annotation tool ELAN [68,69].

Analysis was done by one native Norwegian researcher with medical background(JN) and one with working knowledge of Norwegian who had expertise in the analysis of face-to-face clinical interactions (JG), using both the transcripts and video files of the consultations. We used *microanalysis of face-to-face dialogue* [70], an inductive video analysis method that allows a systematic and exhaustive identification of qualitative phenomena, thus rendering them quantifiable. JN and JG proceeded through the video analysis together, gradually discerning which criteria were important for identifying when physicians were using each strategy. During analysis, two key sources drove analytical decisions about each strategy: (1) the trainers' descriptions of their rationale and overarching teaching aims, and (2) linguistic literature and knowledge of language use in interaction.

2.2.1. Strategies 1 and 3: mapping the patient's preferences and needs, checking the patient's understanding

The analytical process to define, extract and count "mapping patients' needs and preferences" and "checking patients' understanding" involved iterative work that ensured the analytical decisions were systematic and exhaustive. Two researchers (JN and JG) conducted this analysis together, marking relevant utterances in the transcript to retain their sequential context. First, analysts accumulated candidate utterances that appeared to exemplify the strategies and articulated the underlying rationale for each. They then compared the collected candidates and expanded the description of the rationale, gradually developing and refining an operational definition and a detailed set of inclusion and exclusion criteria. JN presented, discussed, and resolved doubts about the defining criteria and analytical decisions in a group of medical communication researchers familiar with analysis of video-taped medical interactions. Finally, analysts discussed whether the accumulated events/behaviors met all defining criteria, further refining the definitions. For both strategies, patient response was also noted. Table 2 presents the analytical procedure for identifying the strategies, with the Appendix providing examples.

2.2.2. Strategy 2: portioning information

Analyzing information portioning necessitated limiting the amount of material. Roter et al. demonstrated that one-minute *slices* of medical interaction show a consistent, moderately strong pattern of correlation with full-session interaction [71]. JN and JG extracted a one-minute slice of the first information-dense sequences from each video. A more extensive description of how we approached the slice methodology can be found in the Appendix. We annotated the relevant phenomena (physicians' speech, gaze direction, timing and duration of pauses between utterances, and patient responses) precisely to its occurrence in the video. Portioning was defined as a pause following a meaningful, information-carrying instalment during which the physician looked at the patient. We set 300 ms as the minimal duration for a pause, as it was immediately noticeable as a pause and within the range of 200 ms (the minimal amount detectable in conversation [72]) and 500 ms [73]. We annotated all such pauses then determined whether each was preceded by the physician stating a meaningful instalment of information and whether the physician looked at the patient during the pause. Pauses over 300 ms that did not fulfil these two criteria were "non-portioning pauses"; see Fig. 1. To account for individual differences in speech rate, we also counted the number of words each physician spoke during the 1-minute slice.

To check whether portioning worked as expected in the interaction, that is, whether the patients took the opportunity to respond that the physician had provided, we noted whether the patient responded to portioning and non-portioning pauses.

2.3. Statistical methods

2.3.1. Definition of variables

JN and JG counted how many times physicians used each strategy. For the portioning strategy, we operationalized information portioning as the *mean instalment length*, that is, the number of words the physician spoke during the 1-minute slice divided by the number of times portioning was used [67]. Further, we defined patient *responsiveness* as the proportion of portioning and non-portioning pauses that elicited a patient response.

Table 2
Strategy, Rationale, Analytical definition with examples, Observed frequencies.

Communication strategies	Training rationale	Analytical definition	Examples of use of the strategy in the interaction	Observed frequencies
Mapping the patient's preferences and needs	Map the patient's level of medical knowledge, needs, and preferences.	Questions to ascertain the patient's level of medical knowledge and what they wish and need to know.	"Du er sykepleier, jobber du innen nevrologi?" (You are a nurse; do you work in neurology?") "Hva, hva har du hørt om, om type andrelinje-medisiner fra før?" ("What, what have you previously heard about, about second line drugs?")	Mean number of preference mapping questions throughout the consultation
Portioning Information	Give the patient time to reflect. Invite feedback.	Pause > 0.3 s, following a meaningful, information-carrying instalment while the physician is looking at the patient.	"Du har jo allerede vært inne på at to av disse midlene gis /non-portioning (np) pause/ intravenøst /portioning (p) /" ("You have already mentioned that two of these drugs are given /np/ intravenously /p/")	Mean number of words per use of portioning in a one-minute slice.
Checking the patient's understanding	Check if the patient has received and understood the imparted information.	Requests that the patients verbalize imparted information back.	"Husker du de medisinene vi har snakket om i dag?" ("Do you remember any of the drugs we have talked about today? ") "Husker du NOE av bivirkningene til, til medisinene?" ("Do you remember anything about the side effects of, of the drugs? ")	Mean number of requests that the patients verbalize imparted information back throughout the consultation.

2.4. Analyses

2.4.1. Applying the definitions to the RCT videos

To test the applicability of the definitions, we used the whole dataset of 34 videos. In the RCT, the intervention did not change the primary outcome [58]. Accordingly, we did not expect major changes in the physicians' behaviors following the intervention. We used the framework of generalized linear mixed models (glmm) with the intervention as a fixed effect, the physician identity as a random intercept effect, and likelihoods chosen appropriately for each behavioral outcome variable (see Table 4).

2.4.2. Validation of portioning and non-portioning pauses

We used a chi-squared test to compare responsiveness for portioning and non-portioning pauses respectively, in order to validate the quality of our definition of portioning and non-portioning pauses.

3. Results

3.1. Assessable definitions of the three strategies in the interaction

The main results of the study are definitions of how physicians manifested the strategies taught in the course in their interactions with patients. We achieved an operationalization of each of the three communication strategies into specific, observable behaviours that could be measured and counted. Table 2 reports an overview of how we operationalized the three strategies, from their training rationale, to the analytical definition, the final numerical result of how to measure them in the interaction, and their expected/desired change. Table 3 reports details about the defining (inclusion and exclusion) criteria for each strategy. The Appendix provides examples of the inclusion and exclusion criteria.

3.2. Validation of portioning vs. non-portioning pauses by measuring responsiveness

Whereas after the 245 times physicians used portioning pauses, patients responded 222 times (91%), after the 191 non-portioning pauses, patients responded only 43 times (23%). The difference was highly significant ($p < 0.001$).

3.3. Applying the definitions in the context of an RCT

3.3.1. Mapping patient preferences and needs

16 of 17 physicians used this strategy pre-intervention, and all did so post-intervention. In Table 4 we report physicians' use of the mapping strategy pre- and post-intervention (Table 4).

3.3.2. Information portioning

We found 436 pauses ≥ 0.3 s in the 1-minute slices from all 34 encounters. Of these, 245 met the definitions for portioning while 191 did not. Table 4 shows mean findings in pre- and post-intervention encounters.

3.3.3. Checking the patient's understanding

The mean number of requests that the patients verbalize imparted information back throughout the consultation was 0.12 pre-intervention (2 out of 17 physicians used the strategy), and 0.29 post-intervention (4 out of 17 used the strategy). Mean change = 0.17).

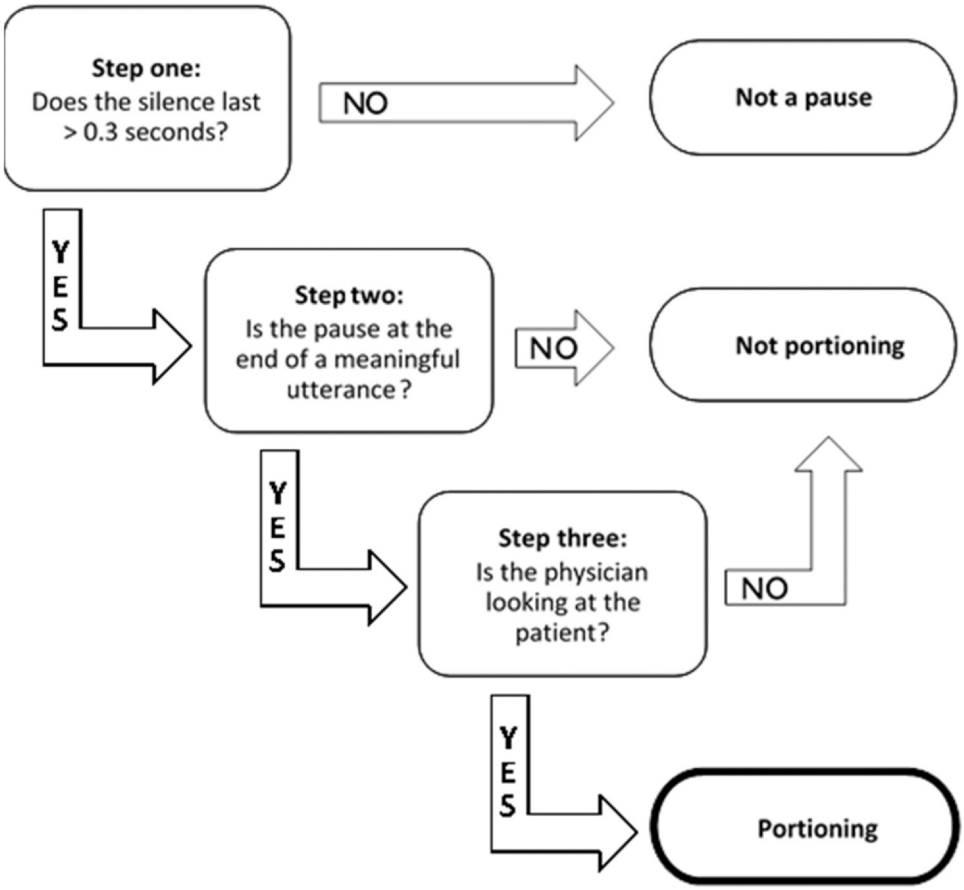

Fig. 1. Main decision steps of pause analysis.

Table 3
Defining criteria of the three strategies.

Communication strategies	Inclusion criteria	Exclusion criteria
Mapping the patient's preferences and needs	a) Asking for the patient's knowledge/thoughts around: • current situation, practical and otherwise • current treatment • a change of medication • possible pros/cons/effects/risks with new treatments • current test results or findings a) Explicitly asking the patient which information he/she wants. b) Asking about the patient's medical knowledge. c) Making sure that the information gathered from the patient about her wishes and preferences is correct. d) Summarizing with an element of probing whether the patient needs more information.	a) Questioning the patient about • Current symptoms, side-effects, medication. • Possible child-bearing wish. • Family medical history • Own medical history • Previous tests a) Reacting to patient volunteering information with a formulation that included repetition only. b) Engaging in small-talk. c) Summarizing information given by the patient. If it is merely a summary, it is also considered a formulation and is thus excluded. d) Posing questions after giving the main body of information to find out if the patient leans towards a preferred choice. e) Posing questions after giving information, checking if the patient is listening/following. This falls under the area of checking for understanding. f) Posing questions as part of closing sequence
Portioning Information	a) The physician making a pause • > 0.3 s • following a meaningful, information-carrying instalment • while looking at the patient.	a) The physician making a pause • < 0.3 s OR is > 0.3 s but • following an incomplete instalment • OR • while looking away from the patient.
Checking the patient's understanding	a) Questions to check if the patient remembers a specific topic. b) Explicit request for the patient to verbalize given information back.	a) Small talk. b) Questions posed after the main body of information giving to find out if the patient leans towards a preferred choice. c) General yes/no questions (that don't specify the topic). d) Questions posed as part of closing sequence. e) The physician summarizing information for the patient. f) Questions that project an affirmative answer.

Table 4
Use of the three strategies in 17 pre-intervention and 17 post-intervention interactions.

		Total sample mean (N = 34)	Pre-intervent. group mean (N = 17)	Post-intervent. group mean (N = 17)	Change of mean	Co-efficient	Std. error	P-value[a]
Mapping needs and preferences[b]		5.03	5.29	4.77	-0.52	-0.05	0.08	0.486
1- minute slices	Portioning[b]	7.21	7.35	7.06	-0.294	-0.02	0.06	0.749
	All pauses[c] ≥0.3 s	12.82	13.88	11.77	-2.118	-0.08	0.05	0.069
	Non-portioning pauses[b]	5.62	6.53	4.71	-1.824	-0.17	0.07	0.024
	Instalment length[c,d]	21.95	21.99	21.92	-0.065	0.00	0.07	0.982
Checking for understanding[b]		0.21	0.12	0.29	0.17	0.70	0.40	0.079

[a] P-values just for the reader's information, we do not use these for formal significance testing in this study.
[b] Poisson distribution.
[c] Log Gaussian distribution.
[d] Number of physician words per portioning.

4. Discussion and conclusion

4.1. Discussion

With this study, we describe detailed methods for how to identify and quantify three key communication strategies for sharing complex medical information in physician-patient interaction. Assessment indications from this study can be reproduced and used in further studies to assess information sharing strategies in medical interactions and test the effect of communication interventions on clinicians' behaviors. In a future intervention study designed for the measurement of both Kirkpatrick level 3 and 4 outcomes, this method can help quantify different behaviors' effects on primary outcome.

4.1.1. Methodological findings: reproducible assessment methods of complex communication skills

Research-trials proposing to test the efficacy of training methods involving information-giving strategies generally struggle with reproducibility. While it may be relatively straightforward to reproduce a drug dosage to test its efficacy, it is far less straightforward to reproduce a communication strategy across multiple patients, since human behaviour and interaction are much more complex and prone to variations than drugs that interact with biology [74]. All steps - from teaching strategies to using them - involve inherently unique dialogues and dynamics between people. That is, strategies are invariably taught differently by different educators, perceived and internalized differently by every learner, and, in the end, used differently with every patient. Acknowledging this problem should encourage researchers to strive towards describing their interventions in great detail, taking control of those dynamic pieces of the puzzle. Note that we have not described the teaching intervention in detail here, since the evaluation of the intervention is not the point of this paper.

By drawing on multidisciplinary expertise from clinical medicine, linguistics, conversational analysis and educational psychology, we managed to define our assessment methods and measures in a highly reproducible manner. Methodological findings provide unique materials for those who aim to evaluate similar training interventions.

4.1.2. Intervention evaluation

We did not aim to measure the effect of the intervention on behaviors, as the RCT was designed for a different primary outcome. The evaluation can, however, be useful in two ways; it can be read as part of a validation, providing information about what can be expected in terms of pre/post behaviour changes. It can also be used as an example of how to use the assessment tools and appropriate statistical methods to compare pre- and post- findings (as in Table 4).

Nonetheless, it is interesting to explore the findings, even though they are secondary. A previous study on the same data demonstrated that the training intervention did not result in significant improvements in patient recall [58]; thus, the current study shows some predictive validity in that the physicians' behaviors did not change either. If the current study would have shown significant physician behavioural change concerning our three strategies, we would have had to question whether the discrepancy was due to our definitions lacking validity or the course content itself.

4.1.3. Strengths

The study is based on data (video recordings of encounters between physicians and real patients) that enabled us to observe the presence or absence of the particular communication behaviours taught during a training intervention. Multiple cameras ensured a face view of both patient and physician simultaneously. The

multidisciplinary approach with input from linguistics allowed to define and quantify minute phenomena in a reproducible manner.

Furthermore, there are some indications that support the validity of this work. The lack of significant results is in line with previous findings that indicate that short communication trainings are less successful than longer ones [75]. Our results are also consistent with previous findings from the same intervention focused on patient information recall [58]. Finally, we found that the pauses we had defined as portioning elicited a significantly higher response rate from patients than non-portioning pauses. This is in line with previous research demonstrating that speakers mobilize listener responses by looking at them [57].

Other strengths include the fact that the analyses developed in this study builds on a foundation of basic research in language and social interaction. For example, we took into account how interlocutors use gaze to mobilize addressee responses [56,57,76], or how speakers use instalments to convey complex information [33,35].

4.1.4. Limitations

This study has some limitations. First, the fact that the MS patients were not de facto in need of treatment escalation may have limited the generalizability of our findings to real-life situations. However, the physicians reported that they found the consultation realistic and recognizable. Patients reported the situation as realistic and a foreseeable next stage of the MS disease; post-consultation feedback confirmed that the information provided was both useful and emotionally relatable. However, ecological validity could be strengthened in further research on actual (not simulated) interactions. Second, the neurology specialty setting with one specific subtype of patients may limit the generalizability of the findings to other medical settings (e.g., primary care), something that could also be addressed by further validation work focused on assessing whether the operational definitions are useful beyond this setting. Third, one researcher had only a working knowledge of Norwegian. However, all analysis was done simultaneously between the two analysts, and the extent to which the analysis required interpreting nuances in speech and speech delivery could be handled by the Norwegian-speaking analyst. Fourth, there is the possibility of a Hawthorne effect [77]. We used discreet ceiling-mounted cameras to minimize this effect. Fifth, we have not developed a codebook. Finally, for detecting and measuring portioning information, we only analysed one-minute of each consultation. However, Roter et al.'s had demonstrated that thin "slices" of medical interaction are representative of the whole session; without adopting the thin-slice methodology, the intensive, time-consuming analysis we designed and conducted would not have been feasible.

4.1.5. Suggestions for further research

Changing individual physician behaviour is a complex endeavor [78]. It is important that the strategies we use, both when teaching physicians and what we teach them to use, are theory driven and evidence-based [78]. When investigating communication training interventions, researchers and experts often focus on intermediate and ultimate outcomes at the expense of immediate ones. The field would benefit from achieving success in the first step: reaching useful and quantifiable immediate outcomes demonstrating behavioural change. Only by establishing what is necessary to achieve quantifiable behavioural changes is it possible to move meaningfully to intermediate and ultimate outcomes, that is, how the changed physician behaviour affects the patient. Not considering the immediate outcome, physician behaviour, when studying patient outcomes, may obscure issues of causation. More studies are needed to disentangle the complex links between communication skills training, behavioral changes, and physician and patient outcomes.

4.2. Conclusion

With this study, we described detailed methods for how to identify and quantify three key communication strategies for sharing complex medical information in the interaction. Assessment indications from this study can be reproduced and used in further studies to assess information sharing strategies in medical interactions and to test the effect of communication interventions on clinicians' behaviors. The intervention that provided video recordings for this study had no significant effect on the physicians' use of the three communication-enhancing strategies.

4.3. Practice implications

This study provides a detailed description of new, inductively-derived assessment measures to detect and evaluate clinicians' use of communication strategies for sharing complex medical information in dialogues with patients. Such measures can be used to assess current practice or evaluate the impact of communication skills training interventions on clinicians' behavioral changes. The background and motivation for using each strategy can be helpful when developing a training intervention aimed at physicians, as well as the detailed definition and examples to implement and assess them. The study also provides indications about a difficulty in achieving clinicians' behavioral change if the communication skills courses are too short.

Ethics approval and consent to participate

The project received ethics approval from the Data Protection Official for Research at Akershus University Hospital. Sensitive data were protected by maintaining the Akershus University Hospital code of conduct in respect of storing data only within specified permitted access drives and using encrypted hardware. Raw data (video recordings) were only available to JN, JG, and PG by administrative permission granted by the CEO of Akershus University Hospital. The study was considered and exempted from review by The Regional Committee of Southeast Norway for Medical and Health Research Ethics, Reference # 2015/161, as it was deemed to be outside their definitions for medical and health research.

All participants were provided with information about the study prior to giving their written consent to participate and for the consultations to be recorded and used for research purposes. Participants received no compensation. The physician in the images in the appendix consented to this use. Considering that the project involved informing patients about medications and risks related to a later stage of their disease, an MS patient representative and a professor of medical ethics constituted an advisory group for the project. All patients were debriefed as part of an immediately following interview. They received information on how to get medical advice or psychological support in case concerns about their MS condition or treatment were triggered by the consultation.

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CRediT authorship contribution statement

Jennifer Gerwing: Conceptualization, Methodology, Analysis and interpretation of data, Writing- Reviewing and Editing. **Julia Menichetti:** Methodology, Analysis and interpretation of data, Writing- Reviewing and Editing, **Pål Gulbrandsen:** Conceptualization, Methodology, Material preparation, Analysis and interpretation of data, Writing- Reviewing and Editing, Data curation. **Owen Thomas:** Formal statistical analysis, Analysis and interpretation of data, Writing- Reviewing and Editing. **Jenny M. Nordfalk:** Conceptualization, Project administration, Investigation, Material preparation, Data collection, Data curation, Analysis and interpretation of data, Graphic design, Writing- Original draft preparation.

All authors read and approved the final manuscript.

Declaration of Competing Interests

The authors all declare that they have no competing interests.

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Authors' contributions

Concept and design: JN, JG, PG. Acquisition of data: JN. Analysis or interpretation of data: JN, OT, JM, PG and JG. Drafting of the manuscript: JN, JM, PG and JG. Critical revision of the manuscript for important intellectual content: JN, JG, JM, PG and OT. Obtained funding: PG. All authors have read and approved the final manuscript.

Consent for publication

All patients and physicians have given written consent to publication of anonymized content. I confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.

APPENDIX

I. The definitions used for operationalizing the four communication-enhancing strategies.

1. Mapping the patient's preferences and needs
2. Portioning information
3. Checking for understanding

I. Slice methodology

I. The definitions used for operationalizing the three communication-enhancing strategies.

1) Mapping the patient's preferences and needs

The strategy of eliciting the patient's current understanding and pre-existing medical knowledge of their disease and treatment, as well as their information needs and preferences, with the intention of utilizing the response to tailor the level of information giving(Bradshaw, Ley et al., 1975, McCarthy, Waite et al., 2012).

Since we are quantifying these skills in order to count how often each physician uses the strategy, every topic they ask about needs to be counted separately, even if more topics are mentioned in one utterance. Here is an example of multiple questions grouped together: I-36, line 171–172: "Hva har du selv gjort deg for noen tanker om, rundt, rundt forskjellige alternativer? Har du hørt om noen alternativer selv, eller kjenner du noen som har hatt noe annet enn Tecfidera?" (What kind of thoughts have you had yourself of, about, about different options? Have you heard of any alternatives yourself, or do you know anyone who has had anything else than Tecfidera?).

The definition includes:

- Asking for the patient's thoughts around:

o current situation, practical and otherwise

- E.g. I-16; "Er det noe du foretrekker tabletter du, eller? Foretrekker du injeksjoner?" (Is it that you prefer pills, you, or? Do you prefer injections?)
- E.g. I-7 line 289; "vad tenker du om det? (ja altså ee) sier det her [om] MR-en (og sånn) (eller e)" (What are your thoughts about that? (well, you know ee) talking about the MRI (and so on) or eh))

o current treatment

- E.g. I-22, line 55 "Jeg vet ikke hva du tenker rundt, rundt det?" (I don't know how you feel about, about that?) [After discussing how current drugs may not be efficient enough.]

o a change of medication, knowledge/thoughts.

- E.g. I-9 line 91–92. “Nei, det er jo en vurderingssak det da om man skal endre, ehm, behandling eller ikke, eh, hva tenker du selv om det alternativet?" (No, whether to change, ehm, treatment or not, would then be a matter of consideration, eh, how do you feel about that option?)
- E.g. I-17 page 2. “Hva, hva har du hørt om, om type andrelinjemedisiner fra før?” (What, what have you heard about, about second line drugs?) [Would influence the amount and level of information given.]
- E.g. I-2 line 110–112. "Det ene er Gilenya. Har du hørt om.?" (One is Gilenya. Have you heard about.?)

o possible pros/cons/effects/risks with new treatments

- E.g. I-15 line 145–146; “Hva tenker du om bivirkningene da, av den nye behandlingen? Tenker du at det er til å leve med, eller?" (What are your thoughts about the side effects, of the new treatment? Do you think they are possible to live with, or?)
- E.g. I-16 line 76, "Det sier kanskje ikke så mye?"(That may not tell you much?) [After telling the patient they have JC-virus.]
- E.g. I-17 line 245, "Men hva tenker du om, om Gilenya da?" (How do you feel about, about Gilenya, then?)

o current test results or findings

- E.g. I-21 line 21; "Ja. For det har ikke du fått høre før?" (Yes, Cause you haven’t heard that before?) [After telling the patient that results from MRI and blood tests are in.]
- E.g. I-10; line 27; "har du NOE spørsmål i forhold til det sjøl?" (Do you have any questions concerning that?)

o Explicitly asking the patient what he/she wants do know/ are interested in information about.

- E.g. I-21 line 310; “du er interessert i hva bivirkningene er." (You are interested in what the side-effects are.)
- E.g. I-23 line 82; "Ehm, jeg vet ikke om du vil høre litt om de." (Ehm, I don’t know if you want to hear a little about those.)

o Asking about the patient’s medical knowledge

- E.g. I-22 line 148. “Du er sykepleier, **jobber du innen nevrologi**?” (You are a nurse, do you work in neurology?”) [Would influence choice of lingo, perhaps also level of perceived medical understanding])
- E.g. I-1 line 178. “Kjenner du noen som bruker det?" (Do you know anyone who uses that?) [Gilenya]

o Making sure that the information gathered from the patient about her wishes and preferences is correct. (Important because the overall function of checking for pre-understanding is to influence what the doctor should provide information about… so a patient preference should affect what the doctor informs about.)

- E.g. I-22 line 158–160; "Ehm, har du, du, du, hvis jeg forstår deg rett så har du selv ikke noen preferanse ovenfor medikamentet, annet enn at du har hørt at Tysabri er bra, men det betyr nødvendigvis ikke at du, at du på en måte ønsker Tysabri for enhver pris" (Ehm. Have you, you, you, if I understand you correctly, you have no personal preference about the drug, except that you have heard that Tysabri is good, but that doesn’t necessarily mean that you, that you sort of want Tysabri no matter what)
- E.g. I-26 line 64–65; "Men da er du på en måte litt sånn, tenkt litt at det å bytte medisin det er kanskje det beste for deg da?" (But, then you are sort of like this, been thinking that a change of medication might be best for you, right?)

o The physician summarizes information the patient has given. If there is an element of probing for more information, it is included. If it is merely a summary, it is a formulation and is excluded, see below.

- E.g. I-1 line 42 + 44: "For det er bildene du tenker mest på?" (Because you are mainly thinking about the images?)
- Definition does <u>not</u> include

- Questioning the patient about:

o Current symptoms, side-effects, medication
o Possible child wish
o Family medical history
o Own medical history
o Previous tests

(Clarification: Of course, the above topics are also important for the physician and could and should be asked with the intention of utilizing the response to tailor their own information-giving. **But it is not exploring the patients’ understanding.** If the physician asked the patient if a stated child wish had made her feel more restrictive about medication, or if previous side-effects affected how she would choose today, this would be included in the definition. But it has to be about the patients’ views or understanding, not just questions about facts.).

- Physician reacting to patient volunteering information with repetition <u>only</u>. (Term: formulation)

- E.g. I-16 The patient responds to the physician. mentioning Tysabri and Gilenya by saying: “De har jeg hørt om begge to." (I have heard of both of those.) The physician responds “Du har hørt om begge to?" (You have heard of both of those?) *[In the next sentence the physician expands on this by asking "Hva vet du om de?" This, on the other hand, is a checking for pre-understanding.]*
- E.g. I-2 Line 114. [*line 110–113 included for context. "Det ene er Gilenya. Har du hørt om.?" (One is Gilenya. Have you heard about.?) The patient answers "ja."(yes)*]
- Line 114: "Du har hørt om den? Ja?" (You’ve heard of it? Yes?) Line 114 is a formulation confirming the statement above, and is not counted as checking for pre-understanding.

- Small talk.

- E.g. I-26 “Du er litt spent kanskje?” (Perhaps you are feeling a little tense?)

- The physician summarizes information the patient has given. If it is merely a summary, it is a formulation and is excluded.

- E.g. I-36, line 189 “Men om jeg nå forstår deg rett så kjenner du, ut i fra det som har vært, at Tecfidera, og det jeg har fortalt om MR-bildene og sånn, Tecfidera ikke virker å fungere tilstrekkelig og du inne i dine tanker på å prøve å bytte til som fungerer bedre og som er mer effektivt helst." (But if I understand you correctly, you feel, based on what has been, that Tecfidera, and what I have told you about the MRI-images and so on, Tecfidera does not seem to have sufficient effect and you are considering trying to change to something that works better and that hopefully is more efficient.)

- Questions posed <u>after</u> giving the main body of information to find out if the patient leans towards a preferred choice.

- E.g. I-21 “Jeg vet ikke hva du tenker? Ja, det er jo ikke sånn at du må ta NOE sånn endelig stilling." (I don’t know what you are thinking? It is not like you have to make some kind of final decision.)
- E.g. I-7 line 659–661"ja. (.) kan jeg bara helt kort spørre (.) vad kjenner du så spontant (.) ee mellom å fortsette litt til på den medisinen du står på, eventuelt å vurdere litt til (.) eventuelt få litt mer tenke (.) tid? (1) eller å bestemme å skifte i dag." (Could I just ask very briefly. How do you feel spontaneously eh between continuing a little longer with the medication you are on, perhaps giving it some more thought, perhaps having some more time to think? Or making a decision to change today.)
- E.g. I-13, line 138; "Men nå har jeg lagt litt ut for deg, hva tenker du om disse, har du endret NOE mening eller er du." (But now I have lectured some for you, what do you think about these, have you changed your mind, or are you.)

- Questions posed after giving information, checking if the patient is listening/following. This falls under the area of checking for integrated understanding. If it is just a yes/no question, it is however not good enough, and excluded from the definition of checking for integrated understanding.

- E.g. I-14 line 160. “Er du med, henger du med?" (Are you following?)

- Questions posed as part of closing sequence.

- E.g. I-22 page 8; “Eh, er det noe du lurer på rundt disse tingene?" (Eh, are you wondering about anything concerning these things?)
- E.g. I-7 line 747; "det var ikke noe du brinner inne med nå da?" (there’s nothing you have left unsaid, now?)
- E.g. I-35 line 344; "er det andre ting som du, du lurer på, med disse medisinene" (are there anything else that you, that you want to know, about these drugs)

2) Portioning information

Physicians were encouraged to *portion* information when presenting it to patients. “Portioning” refers to stating information in short, understandable units followed by a brief silence, which offers the patient an opportunity to respond.

Example [P35-Dr4] 7:03.27-7:15.23.

In this example, the doctor contributes information about the drug Thyroxine. The physician pauses in between short instalments of information. (Note the example presents only the doctor’s speech, in Norwegian, with an English translation in italics):

1. D: (og) det må man nesten regne med, /**0.89 s**/ men det vil jo /**0.95 s**/
2. *(and) you almost have to be prepared for that, /**0.89 s**/ but it will /**0.95 s**/*
3. tyroksin er jo ikke noen /**0.34 s**/ altså /**0.60 s**/ det er ikke det er ikke noe veldig /**0.75 s**/
4. *you know, thyroxine is not /**0.34 s**/ a /**0.60 s**/ it’s not it’s not any very /**0.75 s**/*
5. veldig alvorlig å få det, man blir avhengig av den tabletten? /**0.54 s**/
6. *very serious thing to get, you become dependent on that pill? /**0.54 s**/*

This is an example of what we saw the physicians do. But to achieve patient involvement and patient feedback, all pauses are not equal. The pauses need to follow a meaningful instalment of information, it cannot just be the physician coughing or considering. In addition, literature shows that response is invited when the physician looks at the patient during a pause(Stivers 2010, Svennevig, Gerwing et al. 2019). Based on this we have looked for a specific use of pauses in the material, named portioning.

To achieve portioning we need the three following ingredients:

1) <u>The pause needs to be short:</u> Definition: > 0.3 s
2) <u>The pause should follow a meaningful unit of information:</u>

Fig. 2. Physician looking at the patient.

We split the pauses over 0.3 sec in the material in two groups:

- o "mid pause" = one that happens in the middle of a sentence, the meaning of the sentence is not clear at that point. (Breathing, thinking, looking for a word, speaking slowly).
- o "end pause" = one at the end of a meaningful utterance. Hints in the prosody/intonation that the utterance is complete, and the information in it is fully interpretable.

3) Physician looking at the patient

Definition: An "end" pause, > 0.3 sonds, in which the physician is looking at the patient.

- Example from video no 22, exempt from slice 09:00–10:00, in Norwegian, with an English translation in italics.

Lege: Ehm /mid/, så /mid/, så når vi skal vurdere hvilket preparat du skal ha, så ville jeg kanskje ikke sett så mye på, på effekten /***END***/, eh, men kanskje mer på andre faktorer /end/. Ehm. du har jo allerede vært inne på at to av disse midlene gis /mid/ intravenøst./***END***/

*Physician: Um /mid/, so /mid/, so when we are considering which treatment you should have, I probably would not look that much at, at the effect /**END**/, um, but maybe more at other factors /end/. Um. you have already mentioned that two of these drugs are given /mid/ intravenously./**END**/*

In the example above, we have two instances of collaborative portioning marked with **/END/.**

Figs. 2 and 3 show the ELAN annotations that accompanied a pause deemed as portioning (when the physician was looking at the patient) and a pause that was deemed non-portioning (when the physician was looking away from the patient).

3) Checking for understanding

The strategy of checking whether the patient have received and understood the imparted information by encouraging the patient to actively explain or summarize information the physician considers important has been shown to be effective for increasing patient retention (Bertakis 1977). The question should specify the topic.

Definition includes.

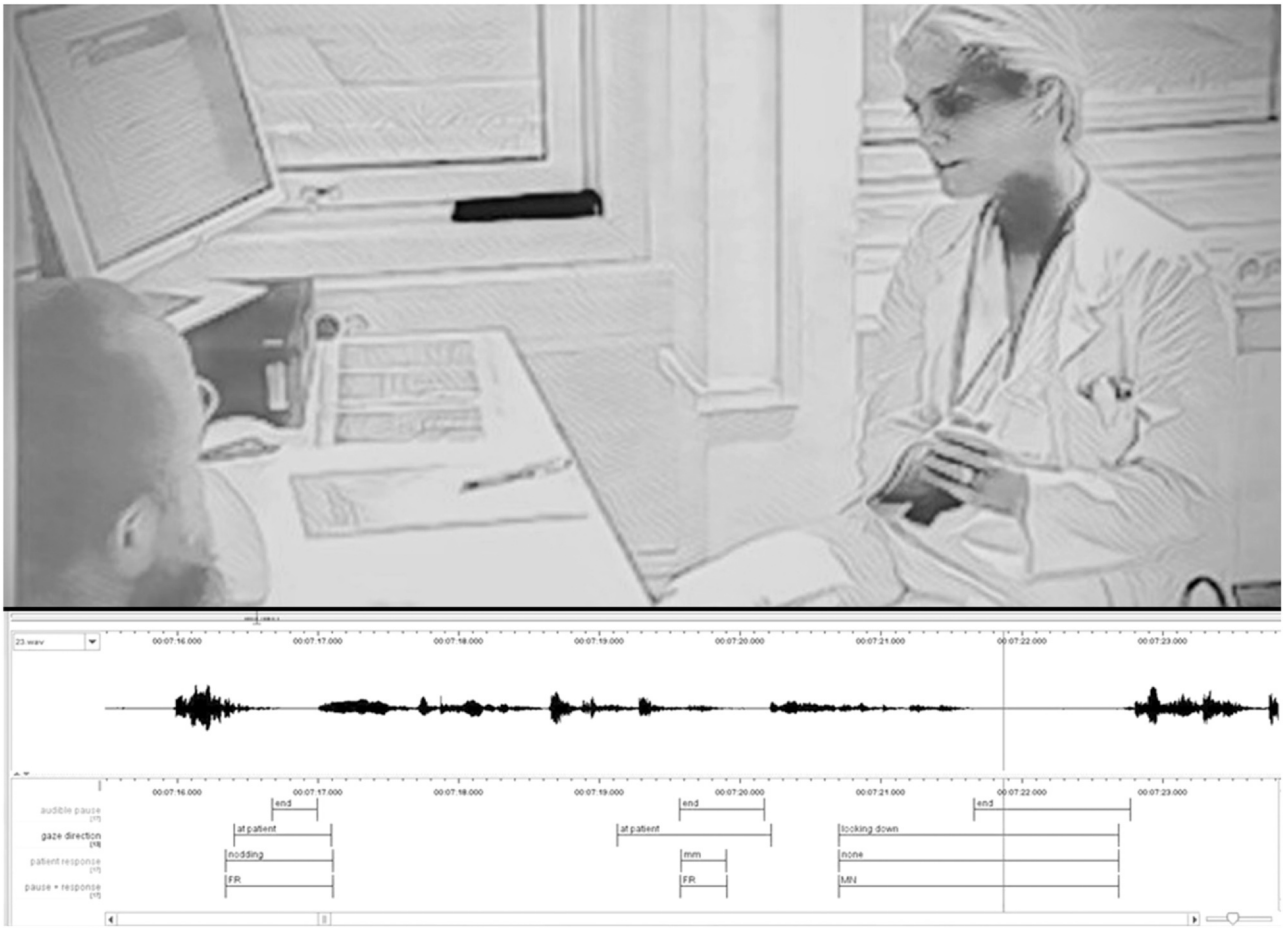

Fig. 3. Physician looking away from the patient.

- Explicitly asking the patient to rephrase, explain or summarize information.
- Explicit questions to check if the patient remembers.

o E.g. I-17 "Husker du de medisinene vi har snakket om i dag?" (Do you remember the drugs we talked about today?) and "Husker du noe av bivirkningene til, til medisinene?" (Do you remember any of the side effects of, of the drugs?)

Definition does not include.

- Small talk

o E.g. I-26 “Du er litt spent kanskje?” (Perhaps you are feeling a little tense?)

- Questions posed after the main body of information giving to find out if the patient leans towards a preferred choice.

o E.g. I-21 “Jeg vet ikke hva du tenker? Ja, det er jo ikke sånn at du må ta noe sånn endelig stilling." (I don’t know what you are thinking? It is not like you have to make some kind of final decision.)

- General yes/no questions (that don’t specify the topic):

o E.g. I-14 line 160. “Er du med, henger du med?" (Are you with me, are you following?)

- Questions posed as part of closing sequence.

o E.g. I-22 page 8; “Eh, er det noe du lurer på rundt disse tingene?" (Eh, do you have any questions concerning these matters?)

- The doctor summarizing information for the patient.

- E.g. I-30 lines 235-238 “Ok. Så oppsummere; Tysabri utmerket medisin, infusjon en gang i måneden, men problemer med JC-viruset. Veldig lav risiko de første to årene, men nivået av antistoffer kan stige og da er risikoen høyere og uansett må man gjøre holdt og front etter to år." (OK. Then summarizing; Tysabri excellent drug, infusion once a month, but problems with the JC-virus. Very low risk the first two years, but the level of antibodies may rise and then the risk would be higher and you would have to stop after two years anyway.)

- Questions that project an affirmative answer

- E.g. I-30 line 21. "Fikk du med deg dette her? Greier jeg å si det på en fornuftig måte sånn at du husker NOE av det?" (Did you get his? Am I able to say this in a comprehensible manner so that you remember any of it?)

Slice Methodology: a more extensive description of how we approached it:

The 34 consultations ranged in duration from 7 to 29 min, with a mean of 20 min. Roter et al. demonstrated that one-minute slices of medical interaction show a consistent, moderately strong pattern of correlation with full-session interaction(Roter, Hall et al., 2011). To study each physicians' use of pauses during information-giving sequences, we therefore extracted a one-minute stretch of information-dense sequences from each video. We found that such density usually took place approximately seven minutes into the consultation, thus we proposed using the first one-minute extract from that point. If this extract did not contain a minimum of three utterances of information-giving, we shifted one-minute forward, continuing to do so until a high-density information minute was found. (To check the consistency of the pattern of the interaction, we also analyzed one additional minute of information delivery from both consultations of three physicians (i.e., six interviews). For these interviews, we chose a consistent topic (a medication option) rather than a particular time, extracting a total of one minute of information provision utterances about the drug alemtuzumab.)

We confirmed the consistency of the pattern of the interaction in the slice methodology by analysing one additional minute of information delivery from both consultations of three physicians (i.e., six interviews). We also were able to test the consistency between two slices from different parts of the consultation (time vs. topic), indicating that the initial slices extracted were indeed representative of the whole encounter[(Roter, Hall et al., 2011).

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III

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Training physicians in providing complex information to patients with multiple sclerosis: a randomised controlled trial

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ABSTRACT

Objective To evaluate the effect of a specific communication training for neurologists on how to provide complex information about treatment options to patients with multiple sclerosis (MS).

Design Single-centre, single-blind, randomised controlled trial.

Setting One university hospital in Norway.

Participants Thirty-four patients with early-stage MS.

Intervention A 3-hour training for neurologists on how to provide complex information about MS escalation therapy.

Main outcome measures Patient recall rate, measured with a reliable counting system of provided and recalled information about drugs.

Secondary outcome measures Number of information units provided by the physicians. Effects on patient involvement through questionnaires.

Methods Patients with MS were instructed to imagine a disease development and were randomised and blinded to meet a physician to receive information on escalation therapy, before or after the physician had participated in a 3-hour training on how to provide complex information. Consultations and immediate patient recall interviews were video-recorded and transcribed verbatim.

Results Patient recall rate was 0.37 (SD=0.10) pre-intervention and 0.39 (SD=0.10) post-intervention. The effect of the intervention on recall rate predicted with a general linear model covariate was not significant (coefficient parameter 0.07 (SE 0.04, 95% CI (−0.01 to 0.15)), p=0.099).

The physicians tended to provide significantly fewer information units after the training, with an average of 91.0 (SD=30.3) pre-intervention and 76.5 (SD=17.4) post-intervention; coefficient parameter −0.09 (SE 0.02, 95% CI (−0.13 to −0.05)), p<0.001. There was a significant negative association between the amount of provided information and the recall rate (coefficient parameter −0.29 (SE 0.05, 95% CI (−0.39 to −0.18)), p<0.001). We found no significant effects on patient involvement using the Control Preference Scale, Collaborate or Four Habits Patient Questionnaire.

Conclusion A brief course for physicians on providing complex information reduced the amount of information provided, but did not improve patient recall rate.

Trial registration number ISRCTN42739508.

Strengths and limitations of this study

- ► Randomised controlled trial design, adapted to health communication research.
- ► Patients with multiple sclerosis with unique insight in the disease and emotional connection to the information.
- ► Reliable measurement of recall of complex information given in free speech.
- ► A small sample.

INTRODUCTION

Multiple sclerosis (MS) immunomodulatory treatment has become increasingly complex as new drugs have been introduced, differing in efficacy, risk/adverse effect profile and administration form.[1 2] In Norway, guidelines for MS treatment issued by the Norwegian Directorate of Health state which disease-modifying therapies should be introduced initially, and which should be introduced as escalation therapy when relapse occurs[3] or if the patient initially presents with a very active disease.[1]

Informing patients with MS about escalation therapy alternatives involves comprehensive exchange of situation-specific information, including risks and effects subject to uncertainty. This information is usually delivered by a neurologist in a task-based but unscripted dialogue with a patient who is experiencing an emotionally charged situation.[4 5]

Medical information should ideally be provided in a way that enables patient autonomy and involvement in treatment decisions.[6] Patients desire tailored information.[7–9] The quality of communication is therefore crucial, if not clearly proven to influence the patients' ability to manage their disease,[7 8 10] at least to improve patient adherence.[11]

Several studies have shown that recall of medical information is suboptimal.[12–17]

Cognitive impairments associated with MS make information processing more difficult.[18–20] Even in early-stage MS, subtle memory disturbance has been shown to be common.[21 22] Improvement of information recall among patients with MS is necessary to avoid lack of patient involvement, adherence and poor outcomes.

A few studies have investigated patient uptake of complex information as an outcome measure; most have directed interventions at patients.[23 24] Intervention studies that link communication training of physicians to patient outcomes in general are rare,[25 26] and to patient recall even more so. The question has been raised whether recall in complex chronic illness management could be improved by changing the communication behaviour of healthcare personnel.[24] Various oral communication strategies have been examined and found to improve patient recall in various ways like repetition,[27 28] simplification of language, pauses, personal relevance[28–30] and structuring.[28 31] One recent study has shown recall rate improvement by information structuring and categorisation, but only for disadvantaged subgroups of a population.[32] Other studies have not showed such an effect, and the phenomena remain understudied in clinical populations.[33] Lehmann *et al* did show that providers should tailor both portioning and amount of information to patient preferences, as those wanting more, also recalled more information.[34]

However, the interventions investigated have usually been long, and most often involved video-vignettes studies or analogue patients, that is, healthy subjects pretending to be patients. Studies have usually tested single, generic strategies, not a set of strategies selected and tailored to the needs of a specific group of professionals and rarely performed in unscripted conversations with real patients. Hence, ecological validity remains unclear. Furthermore, increasing demand on cost control in healthcare makes long training interventions for physicians less attractive to administrators.

In order to accommodate these shortcomings, this study tested a very brief communication training intervention, performed in natural conversations with real patients, although in a fictitious setting, with a set of information provision strategies selected to tailor the needs of physicians working with patients with MS. We tested whether a brief intervention focused on how to deliver complex information, tailored to a selected population of *physicians*, improved *patient* recall rate.

METHODS

Study design

This was a single-centre, single blind randomised controlled pilot trial to determine the effect of brief communication skills training for physicians on patient recall of information provided by the physician. Patients with early-stage MS were randomised to be exposed to a physician either before or after training, see an overview of the study design visualised in figure 1.

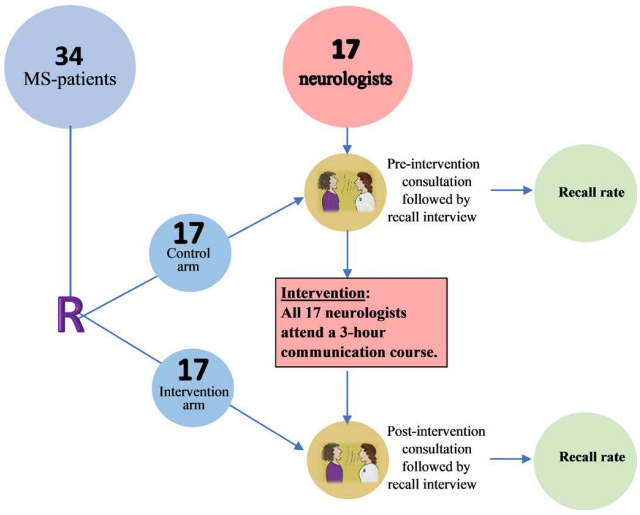

Figure 1 Study design overview. Result: Patient recall rate. MS: multiple sclerosis.

Participants and setting

Patients

The ability to recall information provided depends on its relevance, degree of patient involvement and the emotional state of the recipient.[17 30 35–37] When designing this experiment, we therefore wanted to recruit real patients with MS, who know how it is to live under the sword of Damocles, that is, any time and day symptoms of exacerbations of the disease may appear.[38] To set up an experiment in a communication lab, however, we could not rely on the unpredictable influx of patients in need of escalation therapy. Hence, we approached outpatients identified in the electronic patient records at Akershus University Hospital (Ahus), a teaching hospital in the capital region of Norway with a population uptake area of 575 000 inhabitants.[39] The patients had to meet the following eligibility criteria to be asked for participation and included:

1. Being 18 years old or above.
2. Diagnosed with relapsing remitting MS between 2009 and 2012.
3. Currently on no or first-line treatment.
4. Not yet exposed to a decision about choice of escalation treatment.
5. Not yet received thorough information about escalation treatment options and their pros and cons by a neurologist.

Eligible patients were asked if they were willing to imagine themselves having experienced exacerbations, and meet a physician to discuss further treatment. If willing, they were included in the study.

Physicians

We presented the planned study for the physicians working in the Neurology Department at Ahus on staff meeting and through email. Participating physicians were required to regularly meet patients with MS in their work. To compensate for differences in their level of

experience, participants were provided with an overview of information including risk–benefit stratification for the three most relevant escalation medications commonly used in Norway in 2016: natalizumab, alemtuzumab and fingolimod.[2 40 41]

Setting

Consultations and post-consultation recall interviews with patients were video recorded in a communication lab facility on hospital grounds. The patients were instructed beforehand to imagine that they had recently experienced two unspecific, function-reducing attacks and had undergone an MRI scan and blood tests. They were now to consult with a physician about the tests and scan results, receive information about escalation treatment and discuss options. Except for this fictitious setting, the patients were instructed to use their personal history and behave as themselves. The physicians were fully informed about the fictitious setting. They received information in advance on which and how few details the patients had been given, and were asked not to go into details about previous or recent clinical findings or attacks, nor to examine the patient. They also received an exacerbation history, results of a recent MRI scan showing new lesions and a John Cunningham virus (JCV) antibody index of 0.8,[42–45] all framed as a journal exempt. Physicians were given approximately 20 min for the consultation, to mirror the usual timing of a busy scheduled day. They were instructed to handle the situation as they would have done in their everyday work, basing the discussion of treatment escalation on the individual situation and risk profile of the patient.[1 40]

Intervention

The intervention was a 3-hour communication training course, specifically focused on structured and patient-centred information provision, and targeted at physicians working in neurology. The course was developed and held by a professor specialised in health communication research with extensive experience in teaching medical students and physicians communication skills (PG). It was a condensed version of patient-centred communication skills training[46] with an emphasis on strategies which have been tested or have been expected to improve recall and understanding (creating a safe environment, exploring the patient's understanding and perspectives, prioritising and adapting the amount of information to the patient's prior understanding and needs, using signposting, short sentences, pauses, explanations without jargon and checking for understanding).[27 28 32 47–49] The 3-hour course comprised a 50/50 mix of theoretical instruction and practical training with role plays. Whereas strategies discussed are not specific for communication with patients with MS, examples and practice cases aimed to illustrate treatment decision-making in MS were used. The course was provided in three sessions, for five to six physicians at a time, 21–27 September 2016.

Figure 2 Data collection procedure.

Study procedures

A researcher not involved in the development and delivery of the training (JMN) observed the consultation on-screen in an adjacent room while taking notes with the help of an observational sheet. Immediately after the physician had left the room, JMN performed the recall interview with the patient while the recording proceeded uninterrupted (figure 2). The recall interview guide was strict, with initial open questions, followed by a tailored part in which JMN anchored the questions specifically to the information the doctor had provided during the visit, based on the notes collected during the observation of the specific consultation.

Each physician saw two patients, one before and one after attending the communication training. Pre-intervention consultations took place 16 August–15 September 2016, post-intervention consultations took place 3 October–3 November 2016.

Outcomes

Primary outcome measure

The *from protocol* primary outcome measure was the patient recall rate measured as the amount of information recalled by the patient divided by the amount of information given by the doctor, based on transcripts of the videos. We limited the measurement to information concerning the three most relevant drug alternatives when initiating second-line MS treatment.[41] We developed a specific system for measuring complex oral information transfer in medical consultations, counting the number of information units provided by the physician, and the proportion of these units recalled by the patients.[50] This measure contains a sophisticated system of definitions that enables a coder to break down complex conversation into the smallest countable units that carry meaningful medical information. One quite simple example would be the statement, 'One option is Tysabri, which you get in the hospital as a monthly infusion'. Here, the smallest possible units of information are:

- One option is Tysabri [a]—*name of medication 1p.*
- In the hospital [b]—*administration place 1p.*

- Infusion [c]—*administration manner 1p.*
- Monthly [d]—*administration frequency 1p.*

The system involved three researchers (JMN, MN, PG) and demonstrated high inter-rater reliability (IRR).[50] After establishment of the IRR, JMN coded all transcripts for this study.

Secondary outcome measures

The *from protocol* secondary outcome measure was the effect of the intervention on the mean amount of oral information provided by the physicians. We also explored possible effects on patient involvement using the Control Preference Scale (patient),[51] Collaborate[52 53] and the Four Habits Patient Questionnaire,[54 55] all of these after the consultation.

Sample size estimation

The study was designed as a preclinical trial. No previous ways of measuring orally provided information were available, so the numerical effect size of the measure we developed,[50] as well as its natural variability, was unknown. For a high effect size, we decided to consider the SD of the measured effect as proxy of the average effect of the intervention. Under standard assumptions of a two-sided t-test of statistical significance at 5% and 80% power, 16 patients in each arm of the study were necessary.

Randomisation

An independent statistician performed the randomisation of patients agreeing to participate. The R-method sample (1-42, 21) was used to draw a random subsample of size 21 from the set of 42 patients (figure 3). The four last patients on each list were given substitute status. The random sample was generated without any blocking or stratification restrictions beyond its size. JMN enrolled participants and assigned them blinded to either the control or the intervention group.

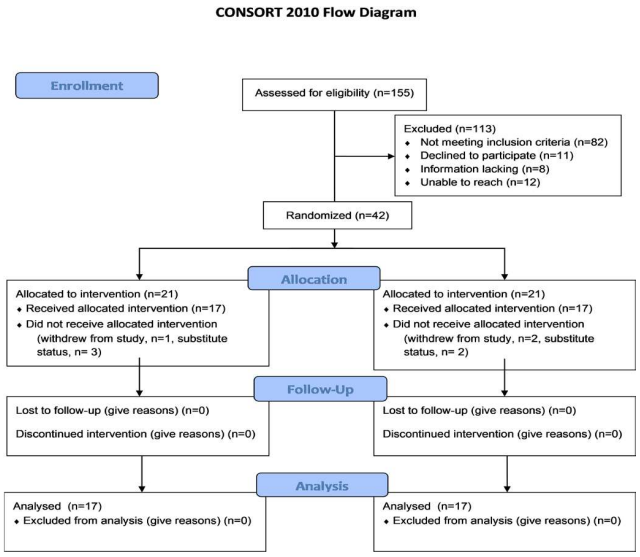

Figure 3 CONSORT 2010 participant flow. CONSORT, Consolidated Standards of Reporting Trials.

Statistical methods

We investigated the effect of the intervention on the recall rate, alongside various secondary outcomes. This was done with separate generalised linear mixed models, using the doctor ID as a random effect and the variables of interest as dependent variables and fixed effects. Likelihood functions were chosen appropriately for the distribution of the dependent variable. Standard maximum likelihood estimates inference was pursued, giving corresponding confidence intervals and p values.

Pre-trial registration

The trial was registered in ISRCTN (www.isrctn.com) on 23 June 2016 (registration number: ISCRTN42739508).

Patient and public involvement

A representative patient with MS and a professor of medical ethics constituted an advisory group for the project.

RESULTS

Participants

All participants, patients and physicians, were included between 12 April 2016 and 2 May 2016. Among approximately 60 resident or consultant physicians employed at the Department of Neurology at Akershus University Hospital, 17 agreed to participate. All provided informed consent. Ten were male (59%), median age was 39 (range 29–57). They had between 2 and 29 years of work experience (median=11) (table 1).

Patient recruitment is shown in figure 3. Out of the 53 eligible patients with MS we reached, 42 agreed to participate and provided informed consent (79%). They were randomised into two groups, each with 17 participants and 4 substitutes. Finally, 34 participated in the study. Median age was 48 (range 21–66 years old). Twenty-five were female (table 1).

An overview of the participant flow is shown in figure 3. Three patients opted out after the study had begun, but before partaking, and was replaced by substitutes already randomised to the same arm.

Both pre-intervention and post-intervention consultations lasted on average 21 min (range 8–29 min, median 20 min). From the consultation transcripts, 1652 physician statements containing information about the three predefined drug alternatives were identified.

Primary and secondary outcomes

The recall rate was 0.37 in the pre-intervention group and 0.39 in the post-intervention group. When predicting the recall rate with the intervention using a binomial likelihood, we found the general linear model covariate coefficient parameter 0.07 (SE 0.04, 95% CI (−0.01 to 0.15)), p=0.099.

The average number of oral information units provided by the physicians before and after the intervention were 91.0 and 76.5, respectively. When predicting this a priori

Table 1 Participant characteristics; neurologists and patients

	Neurologists			Patients			
	(n)	(%)		(n)	(%)	Control arm (n)	Intervention arm (n)
All	17	100	**All**	34	100	17	17
Female	7	41	Female	25	74	12	13
Male	10	59	Male	9	26	5	4
Age by first consultation			**Age**				
<36	3	18	21–30	3	9	1	2
36–45	10	59	31–40	6	18	2	4
>45	4	24	41–50	16	47	10	5
Years of clinical experience			51–60	7	21	3	4
<5	4	24	61–70	2	6	0	2
6–10	3	18					
11–15	6	35					
>15	4	24					

secondary outcome with the intervention using a Poisson likelihood, we found the coefficient parameter −0.09 (SE 0.02, 95% CI (−0.13 to −0.05)), p<0.001. When predicting the recall rate with the amount of information provided, we found the coefficient parameter −0.29 (SE 0.05, 95% CI (−0.39 to −0.18)), p<0.001.

We found no significant effects of the intervention on patient involvement using the Control Preference Scale, Collaborate or Four Habits Patient Questionnaire. We also did not find effects of the patient's gender or age on recall rate.

DISCUSSION

We embarked on this study knowing that hospitals are reluctant to spend resources on extensive courses if strong effects are not demonstrated, and hoping that focus on a simple set of instructions could render a physician behavioural change strong enough to have a detectable effect on patient recall in a small pilot study. We did this, even though two systematic reviews on the effect of general communication skills courses suggested that brief interventions consistently yielded small effects.[23 56] However, some papers suggested that courses of 5 hours or less could have effect.[57–60] These studies addressed emotional communication, patient participation effect[57 58 60] or a very simple instruction about *one* medication,[59] and did not introduce patient adjusted information provision. Neither did they measure effect of the intervention by actual measurement of patient recall. Our study encompassed tailored information giving in a free dialogue with a real patient. Tailored information provision is a complex task, particularly so in the case of involving real patients in decision-making about second-line treatment for MS, which requires that they be well informed about pros and cons of options. The information given in our dataset was a lot more complex than in the studies referenced above. Our study suggests that complex information giving tasks require more extensive training than a 3-hour course to achieve substantial changes in patient recall, at least in decisions as difficult as choice of MS treatment.

In accordance with the principle of prioritising information tailored to the patient,[34] which was one of the strategies taught to physicians in our training, we observed a significant decrease in the amount of information provided by physicians (secondary outcome) after having received the training. We also found that the recall rate decreased with increased amount of information provided, which is in line with previous findings.[35 61]

Questionnaires did not document changes in patient involvement. We did not expect to find changes in such proxy measures in a small pilot, particularly as the intervention was directed foremost to improve information provision, not patient involvement. However, in case we had found changes in patient involvement, we could have explored associations between observed physician behaviour (not reported in this paper) and involvement.

The strengths of this study, besides the randomised controlled trial design, are several. Real patients with MS could easily envision the fictitious position they were in during the consultation, so that information was highly relevant and with potential to evoke emotions. The physicians were not instructed to provide a prefixed set of information, but rather inform the patients according to what happened in the encounter, closely resembling real clinical situations. The recall interview used a technique with questions specifically anchored to the information that had been given, thus providing memory cues without 'helping' the patient. The effect measure was direct recall as fraction of information provided, not more commonly used proxy measurements using questionnaires.

Patients were blinded to training status of the physicians. Furthermore, more female than male patients

participated (ratio 2.8), in accordance with population-based epidemiological data and data from the Norwegian MS Registry, in which the female to male ratio ranged from 1.7 to 2.7,[62] suggesting that recruitment was not gender biased. The distribution of patient gender on pre-intervention and post-intervention observations was similar. There was no attrition, so we had a complete set of data, and only three substitutions among patients. The substitutes were already randomised, so an intention-to-treat analysis was not necessary.

There are also limitations. First, our small sample. With a larger sample we might have been able to show smaller effects. The premise of choosing a small trial and expecting a high effect size proved too optimistic.

Second, the design of our study calls for caution in making causal inferences. As previous researchers have emphasised,[63 64] the link between physician training and patient recall is indirect, and mediated by what actually happened during information provision sequences in these meetings: In other words, the lack of an effect on recall could be due to a lack of change in how the information was provided, even though the amount was reduced. Such a result would implicate something lacking in the training *intervention*. Equally possible is that the physicians applied what they were taught, but that this had no effect on patient recall. This result would call into question the *content* of the training course, while highlighting the efficacy of its methods.

It is a limitation that it was not feasible to do the study with patients in a real treatment escalation situation. The fact that it was not their own treatment that was being discussed may have affected their recall. This would be true for all patients, however, regardless of the training status of the physician they consulted with.

Treatment fidelity was not measured for physician training in this study, but whether they changed some of their behaviour according to the teaching intervention is briefly explored in a qualitative study that showed how to define and assess quantifiable outcomes for three of the information sharing strategies taught in this intervention. It did not show significant effects on the physicians use of those three strategies.[65] We did endeavour to implement the training correctly and consistently for all participating physicians. Patient consultation fidelity was not measured. The amount of time available, setting and situation were, however, identical for all consultations.

Recall was only measured immediately after the consultation. It would have been interesting to have additional patient recall results after an amount of time had passed. On the other hand, this might have led to a risk for contaminated results, as patients in the meantime may have discussed with others or read other information. There is also a risk that the fictitious situation would make the patients less prone to remember multiple facts, as they would not discuss details with spouse or relatives in order to actually choose a treatment.

The research team that made this analysis was, with the exception of JMN, blinded to the intervention status of the transcripts from the consultations and recall interviews. Observer bias cannot be ruled out, although JMN made efforts to ignore not being blind. Some results suggest the measurement is indeed valid: (1) the measurement system was rigorously developed, yielding high IRR,[66] (2) there was no significant negative effect of increasing age within the age span 21–66 years on recall rate, and (3) recall rate lessened with increased amount of information provided. These observations concur with findings in previous studies.[47 67 68]

We did not test pre-study health literacy, collect data on education levels nor did we make a neuropsychological assessment of the participating patients. This was abstained because we feared it could be a stressor that might influence performance. In retrospect, post-visit assessments of health literacy might have shed additional light on our findings. Finally, all the participating physicians were volunteers, and we do not know their baseline skills or motivation. Motivated physicians[46] and physicians with lower skills benefit the most from training.[69]

CONCLUSION

We were able to demonstrate that a 3-hour course in providing complex information about treatment options to patients was sufficient to improve physicians' ability to prioritise information. We found a significant negative association between the amount of information provided and recall rate, supporting previous findings that information provision should be limited to what is most relevant to the individual patient. Despite these effects, we could not demonstrate that patient recall rate improved significantly (p=0.099) in this study. There are still huge knowledge gaps in our understanding of what happens along all the steps from communication trainer to the physician to the patient's recall, and further research is needed in this field.

Practice points

Patients with MS recalled less than 40% of information provided to them, and the recall percentage decreased the more information they received. Improving neurologists' ability to enhance patients' recall of complex information requires more extensive training than a 3-hour session including role-play practice.

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Contributors PG: Conception and design, methodology, material preparation, analysis and interpretation of data, writing—reviewing and editing, data curation. TH: Conception and design, methodology, material preparation, analysis and interpretation of data, writing—reviewing and editing. OT: Formal statistical analysis, analysis and interpretation of data, reviewing and editing. MN: Design, methodology, material preparation, analysis and interpretation of data, writing-reviewing and editing. JMN: Project administration, investigation, design, methodology, material preparation, data collection, analysis and interpretation of data, writing-original draft preparation, reviewing and editing, data curation, guarantor. All authors read and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants but the Regional Committee for Medical and Health Research Ethics (Southeast Norway) decided that this experiment is exempted from review (date: 24 March 2015). Reference ID # 2015/161 exempted this study. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. The data owner is Akershus University Hospital. Requests for anonymised data should be directed to coauthor Professor Pål Gulbrandsen.

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