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An intervention to improve complex information provision to multiple sclerosis patients in need of treatment escalation: 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 multiple sclerosis (MS)patients.

Design: Single-centre, single-blind, randomised controlled trial.

Setting: One university hospital in Norway.

Participants: Thirty-four early-stage Multiple Sclerosis (MS) patients.

Intervention: A three-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: The MS patients were instructed to imagine a disease development, and were randomized and blinded to meet a physician to receive information on escalation therapy, before or after the physician had participated in a three-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 (GLM) covariate was not significant (coefficient parameter 0.07 (SE 0.04, 95% confidence interval (CI) [-0.01; 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; -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, 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: ISRCRTN 32248

Strengths and limitations of this study:

- RCT design, adapted to health communication research
- Multiple sclerosis patients 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 (DMT) 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.[2]

Informing MS patients 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 MS patients 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 health care 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 categorization, 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, i.e., 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, albeit in a fictitious setting, with a set of information provision strategies selected to tailor the needs of physicians working with MS patients. 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-center, 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 visualized in figure 1.

Fig. 1 Study Design Overview. Result: Patient recall rate.

<PLEASE INSERT FIGURE 1 HERE>

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 MS patients, 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:

(a) diagnosed with relapsing remitting MS (RR-MS) between 2009 and 2012;

(b) currently on no or first-line treatment;

(c) not yet exposed to a decision about choice of escalation treatment;

(d) 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 recruited seventeen physicians working in the Neurology Department at Ahus for the study. If willing to participate, they were informed about the following scenario before the study commenced; exacerbation history, results of a recent MRI-scan showing new lesions and a JCV antibody index of 0.8.[40-43] To compensate for differences in their level of experience, they were also 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.[1 44 45]

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 experienced two recent 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. Physicians were given approximately 20 minutes 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.[2 44]

Intervention

The intervention was a 3-hour communication training course, specifically focused on structured and patient-centered information provision, and targeted at physicians working in neurology. The course was developed and held by a professor specialized in health communication research with extensive experience in teaching medical students and physicians communication skills (PG). It was a condensed version of patient-centered 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, prioritizing 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. Examples and practice cases on treatment decision-making in MS were used. The course was provided in three sessions, for 5-6 physicians at a time, September 21-27, 2016.

Study procedures

A researcher not involved in the development and delivery of the training (JN) 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, JN performed

the recall interview with the patient while the recording proceeded uninterrupted (Fig. 2). The recall interview guide was strict, with initial open questions, followed by a tailored part in which JN 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 August 16-September 15, 2016, post-intervention consultations took place October 3-November 3, 2016.

Fig. 2. Data Collection Procedure

<PLEASE INSERT FIGURE 2 HERE>

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.[45] 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 (JN, MN, PG) and demonstrated high inter-rater reliability (IRR) [50]. After establishment of the IRR, JN 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 standard deviation 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.

Randomization

An independent statistician performed the randomization 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. (Fig. 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. JN enrolled participants and assigned them blinded to either the control or the intervention group.

Statistical methods

We investigated the effect of the intervention on the recall rate, alongside various secondary outcomes. This was done with separate generalized 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 (MLE) inference was pursued, giving corresponding confidence intervals and p-values.

Ethics, privacy regulations, and pre-trial registration

The trial was registered in ISRCTN (www.isrctn.com) June 23, 2016, reg. #32248.

The study was considered by The Regional Committee of Southeast Norway for Medical and Health Research Ethics. Reference # 2015/161. The committee decided that as this experiment was not covered by their definitions of medical or health research it was exempted from review. Participants received no compensation for their participation.

Patient and Public Involvement

An MS patient representative and a professor of medical ethics constituted an advisory group for the project.

RESULTS

Participants

All participants, patients and physicians, were included between April 12, 2016 and May 2, 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).

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					

Patient recruitment is shown in figure 3. Out of the 53 eligible MS patients we reached, 42 agreed to participate and provided informed consent (79%). They were randomised into two groups, each with 17 participants and 4 substitutes. 34 finally 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.

Fig. 3 CONSORT 2010 Participant Flow.

<PLEASE INSERT FIGURE 3 HERE>

Both pre- and post-intervention consultations lasted on average 21 minutes (range 8-29 minutes, median 20 minutes). 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 (GLM) covariate coefficient parameter 0.07 (SE 0.04, 95% confidence interval (CI) [-0.01; 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* secondary outcome with the intervention using a Poisson likelihood, we found the coefficient parameter -0.09 (SE 0.02, 95% CI [-0.13; -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; -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 five 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 data set 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-h 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 prioritizing 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 RCT design, are several. Real MS patients 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- and post-intervention observations was similar. There was no attrition, so we had a complete set of data, and only one substitution among patients. The substitutes were also 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. Secondly, the design of our study calls for caution in making causal inferences. As previous researchers have emphasized,[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 was also not feasible to do the study with patients in a real treatment escalation situation.

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 JN, blinded to the intervention status of the transcripts from the consultations and recall interviews. Observer bias cannot be ruled out, although JN made efforts to ignore not being blind. Some results suggest the measurement is indeed valid; a) the measurement system was rigorously developed, yielding high inter-rater reliability,[65] b) there was no significant negative effect of increasing age within the age span 21 to 66 years on recall rate, and c) recall rate lessened with increased amount of information provided. These observations concur with findings in previous studies.[47 66 67]

We did not test pre-study health literacy, 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.[68]

CONCLUSION

We were able to demonstrate that a 3-hours course in providing complex information about treatment options to patients was sufficient to improve physicians' ability to prioritize 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

MS patients 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.

DECLARATIONS

Author contributions

All authors contributed to the study conception and design. Material preparation were performed by Jenny Nordfalk, Pål Gulbrandsen and Trygve Holmøy. Data collection were performed by Jenny Nordfalk. All authors contributed to the analysis and interpretation of data. The calculations were performed by Owen Thomas. Jenny Nordfalk and Pål Gulbrandsen wrote the manuscript with input from all authors. All authors read and approved the final manuscript.

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Ethics approval and consent to participate

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 gave their informed consent prior to their inclusion in the study. 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.

Declaration of competing interests

All authors declare that they have no competing interest.

Data sharing

The data owner is Akershus University Hospital. Requests for anonymized data should be directed to co-author Professor Pål Gulbrandsen.

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FIGURE LEGENDS

Figure 1. Study Design Overview
Figure 2. Data Collection Procedure
Figure 3. CONSORT 2010 Participant Flow Diagram

SUPPLEMENTARY FILES

Registered study record: ISRCTN trial 32248

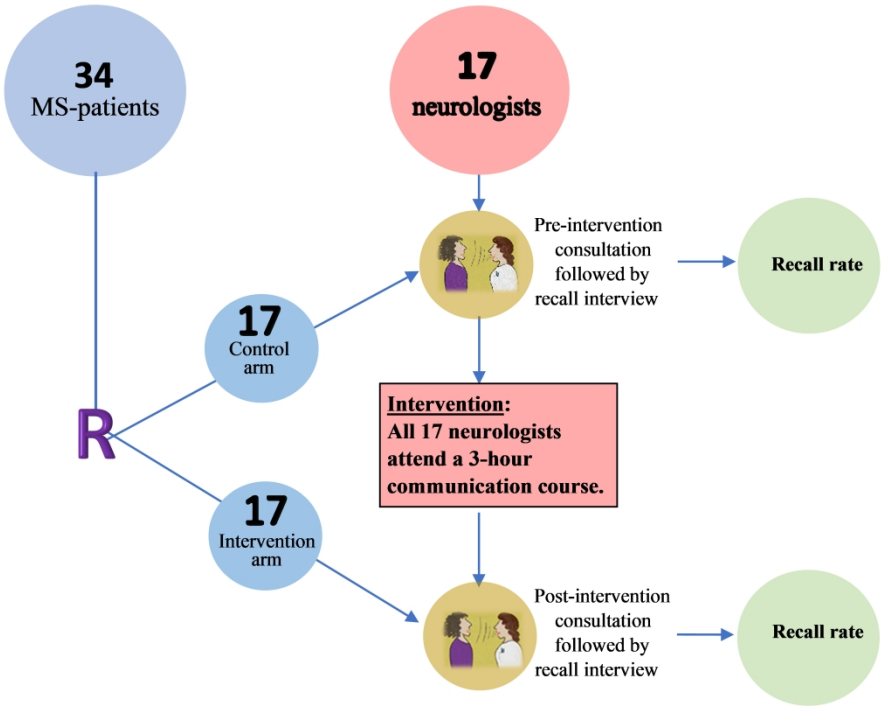

Figure 1. Study Design Overview

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Figure 2. Data Collection Procedure

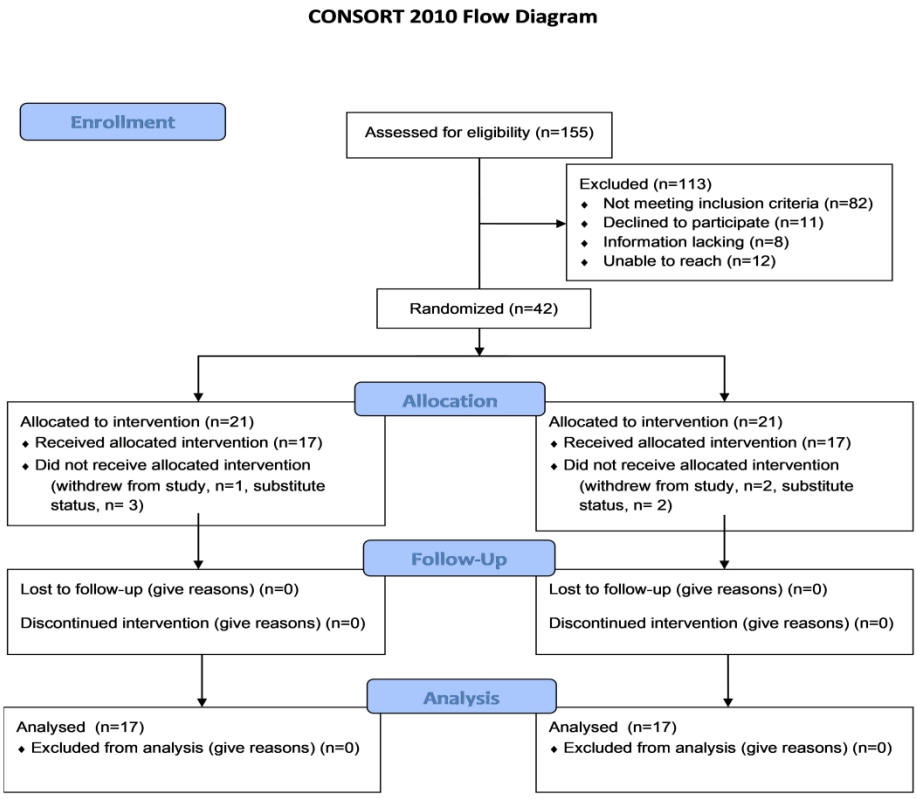


Figure 3. CONCORT 2010 Participant Flow Diagram

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
		Introduction	
Background and objectives	2a	Scientific background and explanation of rationale	3
	2b	Specific objectives or hypotheses	3-4
		Methods	
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	4
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

		assessing outcomes) and how	7
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	7
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	7
		Results	
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	8,9
	13b	For each group, losses and exclusions after randomisation, together with reasons	9
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	8
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	9
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	9
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	9
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
		Discussion	
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	10,11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	10-12
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	10-12
		Other information	
Registration	23	Registration number and name of trial registry	ISRCTN trial 32248
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	EkstraStiftelsen Helse og Rehabilitering (now Stiftelsen Dam) grant no. 7408.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Enabling shared decision making about treatment with multiple sclerosis patients: A preclinical intervention study

Background

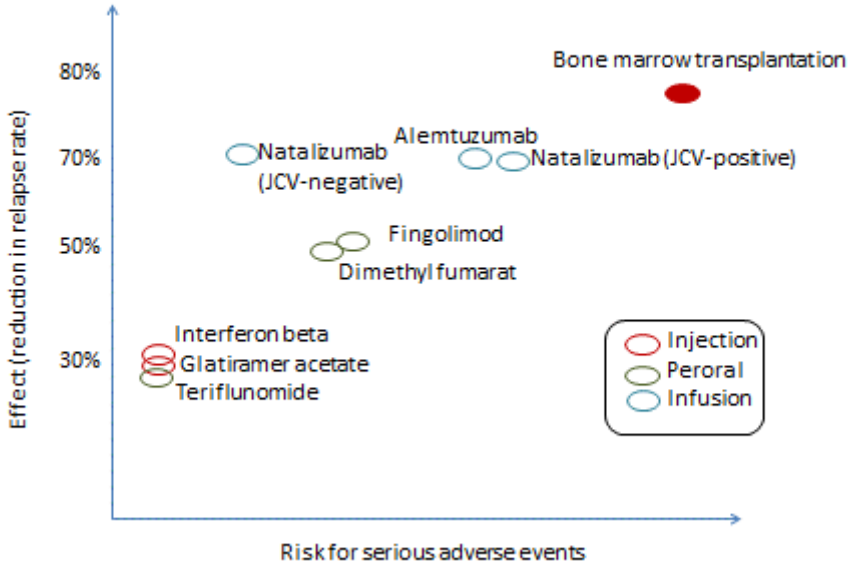
It is an ethical imperative of modern Western medicine for doctors to discuss treatment with their patients [1,2]. This activity is one of several elements included in the concept patient-centered care [3,4]. Two concepts are used, *shared decision making* (SDM) [5-9] and *informed decision making* (IDM) [10]. SDM is more widespread than IDM, and we will use that term in the following.SDM aims to support patients in deliberation and determination around decisions where there is equipoise.

Doctors strive to balance between paternalistic decision-making, appropriate information giving, more or less concealed persuasion or sometimes even complete handover of the decision to the patient [11]. Patients often get confused, particularly when they are given choices without sufficient information about the alternatives or about why the doctor asks them to decide. However, informed and active patients tend to adhere better to the chosen treatment and to be more satisfied with their healthcare [12]. The ability of doctors to practice the involvement of patients in decision making appropriately is still not widespread [13] and has led some critics to abandon the idea [14]. One reason could be that training programs in patient-centered care comprise too many general skills, and results are mixed [15]. This study aims to test simple SDM training initiatives focusing on information giving. New treatment options for multiple sclerosis patients introduce a complex information situation, well suited for development and testing of new, concrete improvements in SDM.

Multiple sclerosis (MS) is the most common disease cause of neurological disability among young adults in Western societies, affecting approximately 10,000 Norwegians [16]. The incidence is increasing, particularly among women [17]. The disease is characterized by an unpredictable course, and has a severe impact on health-related quality of life [18]. Untreated, the majority of patients will over the years develop secondary progressive disease with increasing and permanent disability.

Current immune modulatory treatment in MS may stop disease progression – no drug reverses

established disability [19]. Treatment must therefore start early, before permanent disability develops [20]. Available drugs differ in efficacy, risk/adverse effect profile and administration form. Direct comparisons of effects are complicated as head-to-head studies are generally lacking. Figure 1 illustrates reduced relapse rate versus drug associated risk for serious adverse events.



MS patients will need to be informed about different effect sizes, infrequent and very different serious adverse effects (heart block, hematophagocytic syndrome, encephalitis, progressive multifocal encephalopathy, impairment of vision (macular oedema), possible increased cancer risk) related to the drug alternatives, and all in light of limited experience due to short observation time for the new drugs (compared to the duration of MS) [21-25]. The complexity of the information is reflected in frequent updates of the Norwegian Health Directory guidelines for MS treatment. According to the Norwegian Health Directory guidelines for MS treatment most patients should initially be treated with glatiramer acetate, interferon beta 1a/b, teriflunomide or dimethyl fumarate[21]. Fingolimod, natalizumab and alemtuzumab should be used as escalation therapy if first line drugs fail, and from the beginning in a minority of patients with severe disease. There is, however, room for interpretation in individual cases, reflected in extensive difference in the use of disease modifying MS drugs between counties in Norway. According to the prescription registry, both the total use and the ratio between the

different drug classes differ by more than 50%. These differences cannot be explained by differences in prevalence or incidence, which is quite uniform across Norway [26]. They are therefore likely to reflect differences in doctor (and, less likely, patient) preferences and in tradition related to decision making, and should give rise to ethical concern.

Decision making. The decision on initiating MS treatment is a process involving both the neurologist and the patient, and in many cases also other actors like MS nurses, relatives and friends. There are several factors that make this choice difficult for patients: First, it requires knowledge about the individual prognosis as well as the pros and cons of the treatment options. Second, the decision often has to be made in a period of emotional chaos and distress. In order to involve the patient, the doctor must provide sufficient information. On the other hand, too detailed or otherwise poorly communicated information may enhance uncertainty and despair, and thereby reduce the patient's capacity or wish to be involved in the decision making. The complexity of this decision is reflected by research in Italy and Germany [27,28], with an emphasis on patient information. The task calls for doctors who are well skilled in patient-centered care and SDM.

SDM in medicine is a rapidly growing research field. Most studies on medical decisions and patient-doctor communication have been performed to assess the degree of patient involvement. SDM studies are predominantly descriptive, combining observation of real doctor-patient encounters with patient reported outcomes (mainly various satisfaction scores) after such encounters. Experimental studies are few. Interventions are either more general training in patient-centered care and/or SDM (also done by our group with success [29]), or various preparations of patients (decision aids, pre-encounter information etc) [30]. Training often aims to alter physicians' behaviour by introducing a set of skills, and it is usually difficult to determine exactly which element that explains observed effects on patients. We have not found intervention studies based on the changing of one particular skill. Measurements are also a challenge, and low correlation between instruments of conceptual similarity has been observed [31]. A new promising instrument (MAPPIN'SDM) which

encompasses observations of the decision making process from three angles, the doctor, the patient, and the observer, has been developed recently by a research group we have initiated collaboration with [32].

In the case of deciding whether to start second line treatment in MS, the main challenge is to convey sufficient information in a way the patient can handle in that emotional situation. Unpublished qualitative observations in our own large dataset [29] suggest that this requires that the doctor prioritizes, rations, and portions the information.

- Prioritize: Decide up-front which information that the patient must have in order to be sufficiently informed.

- Portion: Allow a micropause (1-2 seconds) after each sentence to check visually if the patient follows, also providing an opportunity for immediate questions.

- Ration: During the consultation, assess – given the patient's emotional state, questions and the time available – how much additional information to provide there and then, and what and when to provide more.

Of note, this approach is not contradictory to patient-centered communication and shared decision-making. The point is that the doctor has to be more thoughtful about his information giving up-front, and equally aware of the patient's reactions under way. He is also instructed to use clearer sentences and fewer words. By doing so, there is less room for assumptions about the patient and more room for the patient to question.

We propose that a simple intervention where the doctor changes just this part of the communication could render high effect on patient take-up, understanding, and ability to decide what to do. If we can provide evidence that very simple and highly specific changes in communication helps patients and doctors in this challenging situation, it will potentially improve the care of MS patients, and may also provide a model for clinicians in other fields in

corresponding situations.

A new type of translational research. It is rare to see health services intervention studies with trials in different phases, analog to drug effect studies. In communication research it has hardly ever been done. We think it is necessary to conduct proof-of-principle studies in laboratories before implementation in large scale trials. In real – and difficult – clinical situations, it is unlikely that patients, or doctors, will accept to participate in behaviour intervention studies unless prior studies under controlled conditions have shown promising effects. Hence, this proposal is about trying out a behaviour intervention in a lab in order to explore whether this intervention is worthwhile studying in a clinical trial.

Aim of the project

The overall aim of this project is to improve patients' involvement in decision making by introducing small, highly specific behaviour changes of doctors, using the initiation of MS treatment as an example.

Specific subgoals are:

1) To develop a consensus based fact sheet through involvement of an ethicist, neurologists and patient representatives, that designates which information should be given priority in consultations about treatment choices, built on updated knowledge from clinical trials and clinical registries on treatment effects and side effects, and guidelines of evidence based patient information.

2) To observe how doctors communicate treatment options to MS patients, in order to

    (a) Describe today's typical behaviour related to MS treatment decisions, and use this as a validity check for the non-intervention arm in the behavioural experiment.

3) To test the effect of a simple, highly specific communication intervention, established through instructions to doctors, on patients' information uptake, understanding, willingness and ability to make a decision in a communication lab, including

(a) The main effect study.

(b) A study that evaluates the ability of the doctors to adhere to the taught intervention.

Methods

Subgoal 2 is covered by study 1, subgoals 1 and 3 by study 2.

Study 1 – Observation of current practice and preparation for experimental study

We will videotape at least six encounters with different doctors and patients. Videotapes will be used to describe which information patients are given, and how, using qualitative analysis according to Miller & Crabtree [33], and based on observation of specific elements in the Four Habits Coding Scheme (4HCS) [34]. The 4HCS is suitable for measurement of patient-centered behaviour. This real encounter measurement will be compared with the nonintervention arm encounter measurements in study 2 to see if the experimental situation diverges much from a normal situation regarding patient-centered behaviour.

Right after the encounter, the patients will be interviewed by a researcher, who uses a structured interview to map the patient's information uptake, understanding and thoughts about the decision. Doctors will also be interviewed about their experiences in the consultations. The study will be used to inform the creation of the fact sheet (see study 2).

We will include doctors for study 2 among doctors in study 1. Criteria are that we do see a potential for improvement on information giving (habit 4 in 4HCS), and that they have an acceptable standard regarding ability to manage emotional issues (habit 3 in 4HCS). The latter is necessary because in this particular study we do not want to manipulate the affective part of the doctors' communication style, and need to have reasonably well-functioning doctors in that respect. In an exploratory study this is necessary, while in a large scale trial it is not. Any exclusion will be on very strict criteria, e.g. extremely poor empathic performance or

extremely well-functioning information giving (which leaves little or no room for improvement). Our assumption is that all six doctors will satisfy inclusion criteria for study 2. We might need to add encounters until we have a sufficient number of doctors.

Publications from study 1: 1-2 qualitative articles that include quantitative assessments in a communication journal (Patient Education and Counseling) or MS journal.

Study 2 – The experimental study

A panel of an ethicist, experienced neurologists with MS expertise and MS patient representatives (volunteers from the Norwegian MS Society have confirmed willingness) will prepare a fact sheet describing in detail a) the crucial information that has to be given to the patient, and b) optional information that may be given as a result of the natural development of an encounter in which treatment options are presented. Available guidelines will be used, and experience gathered from interviewing patients in study 1 will be taken into account.

Intervention: Participating doctors will meet patients in a communication lab. The doctors will first perform encounters with their current information giving style. Then they will be exposed to a short training session focusing on improved information giving, using prioritization, portioning, and rationing. Afterwards, they will perform encounters using this method.

Participating patients: We will include relapsing remitting MS patients that currently use any of the first line drugs, and who have not previously been exposed to the decision to begin with a second-line drug. Patients will be identified in the electronic patient records at Akershus University Hospital (AHUS), and invited to participate through mail. They will serve as proxies for patients in a real choice situation.

Reasons for choosing such patients are that

- It is very hard for a healthy person to imagine how it is to be an MS patient.
- MS patients treated with first line drugs represent a subgroup of patients that could be

eligible for second line treatment, and are therefore as close to the target population as possible.

- Real patients would be too few within the time frame of this part of the study, which has to be performed in a single center because of the need for a lab facility.

The use of MS patients that are not in a real choice situation could lead to less information uptake ("this is not that important for me") or higher information uptake (being less emotionally involved). So to use such patients is a trade-off, in which we balance feasibility (experimental control, small scale trial, costs) with validity. In our opinion, a large scale multicentre trial where doctors in several sites need training and real patients are involved, is prohibitive unless we have clear indications that the behavioural change we want to induce is possible and proves to improve patients' information take-up and ability to participate in the treatment decision.

Sample size estimation: We want to document a strong effect, as we think this is necessary to convince future doctors to accept and adapt such a behavioural change. We expect a strong effect from the present intervention, since it is simple to learn and tailored to the selected patient population. The scale of measurement will be developed for the present project, so the numerical effect size, as well as its natural variability, is unknown (see outcome variables). Our best guess is that the average effect of the intervention will 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 gives 16 patients in each arm of the study.

Preparation of doctor: The study doctor needs to remember the fact sheet information. The doctor is instructed that the encounter follows recent information about the disease activity of this patient, that warrants a discussion about whether to start with second line drugs or not. Preparation of proxy patient: The patient is told that the study is about how the doctor

communicates (but not anything specifically about the concrete intervention and aim). They are instructed to imagine that the current meeting is a real one, although the doctor will present them to information that is not real. Written informed consent is to be acquired at this point.

Randomization: Participating proxy patients are randomized to receive normal or intervention doctor behaviour, and scheduled to meet in the lab accordingly.
Encounter: The doctor has 20 minutes to his disposal to inform the patient. The encounter is filmed, while the researcher simultaneously observes which information that is given. The doctor will not be interrupted if he exceeds the time limit, and encounter duration will be measured (confounding variable).

Post-encounter interview: The researcher performs a structured interview with the patient, with primary purpose to describe as precisely as possible what the patient remembers of the information he/she received, how the information is understood, whether he/she feels equipped to make a decision, and how the patient feels about this decision. The interview is filmed (for documentation/validation purposes), but concrete data are entered in a prepared data sheet by the researcher during the interview. In addition, the patient will complete a recently developed risk knowledge questionnaire (RIKNOW) (http://www.automsproject.org/) which we are allowed to use by our collaborator Jürgen Kasper.

Post-encounter questionnaires: The patient and the doctor complete post-encounter electronic questionnaires about emotions during the interview [35-37]. These data will be used as independent variables in predictive analyses.

Video coding: The doctor-patient encounter is coded for quality of SDM using either the OPTION instrument [38] or more likely the MAPPIN'SDM instrument [32], and The Four Habits Coding Scheme [34]. The doctor's use of specific intervention techniques is measured

in frequencies and seconds (main explanatory variable). The adherence of the doctor to the priority facts in the fact sheet is measured on a novel scale developed for this purpose (confounding variable). We have not found any similar measure in the relevant literature that could be used for our purpose. We currently perform a qualitative study on existing video material from AHUS, led by postdoc Jennifer Gerwing (see study resources). In that study we identify communication content and clarity in doctor information giving. Her expertise will inform the development of the proposed scale.

Analysis: We will use a standard RCT to determine effect of the intervention, with multilevel approach accounting for interdependency between encounters made by the same doctor. We will also do a secondary analysis using standard linear regressions to determine predictors of patient post-encounter knowledge agreement with fact sheet, and predictors of adherence of the doctors to the prescribed behaviour.

Outcome variables in RCT:

1. The main outcome variable is a measure of patient knowledge about crucial information (as predefined by the fact sheet). The RIKNOW questionnaire, or an adjustment of this (following agreement about contents of the fact sheet), will be used. In addition, as a validity check, the patient's knowledge of prioritized facts is compared to the fact sheet on a scale (5-point from no agreement to high agreement) by a statistician that does not know which arm the data comes from.

2. Other outcome variables
   a. Patient evaluation of ability to be involved in the decision
   b. Patient satisfaction with the doctor's communication about the decision

Of note, we will not perform pre-encounter knowledge tests of the patients, as this could influence the encounters. Randomisation should in principle secure that this does not bias the results.

Publications from study 2: Two publications planned to be published. The effect study will be submitted to a major clinical journal. The study about doctor adherence to the fact sheet will be submitted to a journal about medical education or communication.

Secondary analyses: We aim to publish 1-2 papers on predictors of change.

Timeline, ethics, etc.

2014 The ethics committee application will be prepared and submitted before the start of the funding applied for in this proposal.

2015 Prepare electronic questionnaires. Prepare measurement scales and fact sheet. Recruitment for study 1 and study 1 data collection. Preparations for study 2.

2016 Submit paper from study 1. Study 2 data collection, videotape coding and starting analyses of study 2.

2017 Submit papers from study 2. Beginning secondary analysis. Submit thesis.

The study may extend into 2018 depending on recruitment of the PhD candidate.

Contribution to science and society

Experimental studies on concrete, limited clinical communication behaviours, specifically aimed at improving patients' understanding and thereby helping their involvement in decisions, have previously not been conducted. We hope this approach will lead to better insight in the direct link between information giving skills and information transfer in clinical work. We also aim to provide a new way of thinking in communication skills studies, with experimental studies preceding clinical trials, thereby bringing this field closer to the level of drug testing.

Decisions about long-term treatment have the potential to consume or save resources as the drug regimens may amount to high costs. It is not only in the patient's and the doctor's interest, but also in the interest of the society that these decisions are made as properly as possible.

Study group and resources

Principal investigator: Pål Gulbrandsen is professor of health services research at the University of Oslo (UiO) and AHUS, and has published more than 80 original papers, mostly on the doctor-patient relationship and doctor-patient communication. He has built a research group at AHUS with one completed PhD (plus two in other clinical areas) and three current PhD students studying clinical communication. He also initiated, with professor Arnstein Finset at Dept. of Behavioural Sciences (UiO), the Oslo Communication in Healthcare Education and Research group (OCHER, see www.ocher.no), which is the second largest group in the field in Europe.

Trygve Holmøy is a consultant and professor at Department of Neurology at AHUS. His main research interest is multiple sclerosis. He has supervised five PhD students that have completed their PhD theses during the last years, and has large experience with treating MS patients. He has participated extensively in the development of this project. He will participate in recruitment of patients and doctors, and co-supervise the PhD student.

Fredrik A. Dahl is a senior researcher at AHUS with a PhD in informatics and a postdoctoral in statistics. He has been an important contributor to several clinical studies in AHUS included a previous crossover randomised controlled trial testing the effect of communication skills training. He will supervise the statistical analysis and qualify the randomization procedures. He will have an important role in the secondary analyses, in which the PhD student is not expected to be the first author.

Jennifer Gerwing is a research psychologist and a postdoctoral student at AHUS. She is also affiliated with the University of Victoria, Canada, and has extensive experience with lab studies on clinical communication. She will supervise the video analyses.

External collaborators

Jürgen Kasper is professor at the University of Tromsø and an experienced psychologist with

several years of studies of medical decision making. He is an important collaborator in the project "Autonomy preferences, risk knowledge and decision-making performance in multiple sclerosis patients". His contribution will be his knowledge base in this particular field.

Edward Krupat is professor of evaluation at Harvard Medical School, Boston, US. He is a social psychologist with large expertise in development of instruments for the evaluation of behaviours, and a collaborator of Pål Gulbrandsen for nine years. He will assist the development of measurements.

Kjell-Morten Myhr has for several years headed the Norwegian Competence Center for Multiple Sclerosis at Haukeland University Hospital, where he now is a full professor and consultant in neurology. He has extensive experience in MS research and clinical practice, including clinical trials. He has headed the development of official Norwegian guidelines for treatment of MS. He will participate in development of the fact sheet and in interpretation of the data.

Reidun Førde is a professor in medical ethics at the University of Oslo and has for years worked with problems related to the involvement of patients in decisions about treatment. She will assist in development of the fact sheet.

The expertise of all people mentioned above will be used in the project. The current proposal aims to fund one PhD student, preferably a medical doctor, to run the data collection and deliver a following thesis. This student will be recruited by public announcement.

Costs

AHUS covers expenses related to all listed internal collaborators, estimated to about NOK 500,000 over 3 years. AHUS also covers traveling costs for proxy patients (estimated to max NOK 10,000), development of electronic data sheets (equivalent of 30 hours), and estimated costs related to time used for participating doctors (equivalent of 50 hours). No expenses are

related to the external collaborators. However, there is need to employ video coders, and they need to be trained. We estimate the costs for this training to NOK 100,000. The PhD candidate should attend two international conferences annually (in Europe and the US), for which we estimate the average cost to be NOK 10,000, amounting to NOK 60,000.

At our disposal we have a new communication observation lab inside the hospital, with state of the art equipment delivered by Noldus Inc., Wageningen, the Netherlands. This equipment is provided by the Institute of Clinical Medicine at the University of Oslo. The Dept of Neurology at AHUS has a catchment area of 450,000 people and the responsibility of approximately 700 MS patients (the number of newly diagnosed patients in 2011 and 2012 were 35 and 51, respectively).

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There is no named PhD candidate so this file is empty.

We will primarily recruit a resident neurologist as PhD candidate, alternatively a resident in another

specialty.

Study record 32248

Generated: 23/06/2016 9:08:05
Editorial Status: Submitted

Title and Additional Identifiers

Submission number
32248

ISRCTN

DOI

Public title
Improved involvement of multiple sclerosis patients in discussions about treatment

Scientific title
Enabling shared decision-making about treatment with multiple sclerosis patients: A preclinical intervention study

Acronym

EudraCT number

ClinicalTrials.gov number

Protocol /serial number
2015/FO7408

Condition category

Date Applied
23/06/2016

Date Assigned

Last Edited
23/06/2016

Prospective/Retrospective

Overall Trial Status
Ongoing

Recruitment Status
No longer recruiting

Study Information

Study hypothesis
A 3 hour course in how to provide information will improve MS patients' ability to recall information given by doctors.

Ethics approval
The Regional Committee for Medical and Health Research Ethics (Southeast Norway). Reference # 2015/161. The committee decided that as this experiment is not medical or health research and therefore exempted from review. Date: March 24, 2015.

Study design
This is a preclinical interventional study. MS patients are invited to meet a doctor in a fictitious situation in which they need to discuss a change in treatment with several options (that is; this is not an actual need for this patient, but something that may happen in the future). The doctors meet one patient before and one after they have received a 3 hour course in how to give information. Patients are randomly allocated to meet a doctor before or after the intervention. The randomization is performed by an independent statistician. More patients than needed are invited and randomized, so that if a patient cannot meet, another patient from the same arm of the study can substitute. The patients will not know if they meet a doctor before or after the intervention. This is a single-centre study. Patients are identified in the hospital patient records, and initially contacted by telephone for recruitment.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Trial setting
Hospitals

Trial type
Other

Overall trial start date
01/04/2014

Overall trial end date
31/12/2016

Overall trial status override

Reason abandoned

Condition
Multiple sclerosis. The study object, however, is information provision as part of patient involvement. Results may have value for other patient groups.

Interventions
Patients are not "treated", but exposed to doctors with or without recent training in information provision. The training is a 3 hours course given in small groups of doctors. The content of the

course is simple instruction in important aspects of information giving. All course participants will need to practice the instruction in role-plays. As mentioned earlier, the participating patients are allocated to meet a doctor before or after the doctor has been trained. One researcher observes the doctor-patient interaction and notes all information that is provided. The researcher interviews the patient directly after, first using open questions to elicit understanding and recall, followed by prompted, but not leading questions about information the doctor provided to elicit as accurate recall as possible. Both doctor-patient interaction and post-visit interview are videotaped, and independent coders that will not know if the interaction is pre or post intervention identify and decide whether patient recall of each information the doctor has given is sufficiently precise to represent the information given. Following these procedures we will be able to calculate the percentage of given information that is recalled, and whether there is a significant difference between patients in the pre-course and post-course arms of the study. In addition, we will use a battery of questionnaires (MAPPIN'SDM, Collaborate, Four Habits Patient Questionnaire) to map the patients' evaluation of communication, information provision, and involvement in decision-making.

Intervention Type
Behavioural

Phase

Drug name(s)

Primary outcome measures
The amount of information provided by the doctors that is recalled by the patients.

Secondary outcome measures
Secondary outcomes (questionnaires) will be measured immediately after the visit. We also aim to collect an outcome defined during video observations, how strongly the doctors adhere to the principles of information provision. This will need more time, as one will have to calculate inter-rater reliability of the coders etc. So both the primary outcome measure and this secondary outcome measure is likely to be finalized several months after the data collection is finished.

Trial website

Participant information sheet
The PIS is in Norwegian and available by contacting the principal investigator: pal.gulbrandsen@medisin.uio.no

Eligibility

Participant inclusion criteria
Patients with relapsing remitting MS who currently use a first line drug and who have not previously been exposed to the decision to begin with a second line drug.

Participant type
Patient

Age group
Adult

Gender
Both

Target number of participants
32 is necessary for the trial, but we aim to recruit an additional 10 as substitutes.

Participant exclusion criteria
We have no exclusion criteria.

Recruitment start date
01/05/2016

Recruitment end date
31/05/2016

Recruitment status override

Locations

Countries of recruitment
Norway

Trial participating centres

Trial Centre

Trial Centre Name
Akershus University Hospital

Address
Post office box 1000

City
Lørenskog

Country
Norway

Zip
1478

Plain English Summary

Patient involvement in decision-making requires information provision during medical encounters. Several studies indicate that doctors' information provision often is insufficiently structured, imprecise, characterized by use of jargon, and not adjusted to the patient's needs. This study aims to try out whether a rather simple training session for doctors leads to an improvement in these respects, in a way that helps patients to better recall the information they

received.

Patients with multiple sclerosis often face difficult decisions about choice of treatment. The reasons for this are several: the natural course of the disease is unpredictable but potentially serious, there are several new drugs available with different effects, side effects, and risks, and because of the drugs' novelty long-term effects are not well-known, while the disease itself is life-long usually spanning decades. It is hard, even for a doctor, to keep track of all the information available, and even experts will admit uncertainty about choice of treatment. Patient involvement in these situations is a difficult task. We have decided to focus on the actual quality of information provision, with an underlying hypothesis that if this part functions better, patient involvement will improve as well.

We have decided to design a small preclinical trial in which we hope to identify a large effect of training. The rationale for this is that we think it will be difficult later, on a large scale, to convince busy neurologists that they should go through training if the effect is small. Using this line of thinking, in this study we only need 16 neurologists, meeting two patients each, one before and one after training. Hence, 32 patients will be recruited. Whether they will meet a trained or an untrained doctor is random.

All doctor-patient interactions will be videotaped and post-visit interviews as well. We will calculate how much of the information the doctor provided that the patients remember. We will also ask the patients about the quality of the consultation, in terms of communication, information, and involvement. In addition, we will measure how well the doctors adhere to the training principles.

The training session has been piloted in a different hospital, with gastroenterologists, giving information at discharge from hospital. In this pilot study, data collection has been less rigorous and not included videos. Results using evaluations by doctors and patients are promising.

Our overall aim is that we can find ways to help doctors become better information providers, using condensed training sessions, as one part of the important changes in society regarding patient participation in decisions about treatment.

Results and Publications

Publication and dissemination plan

We plan to publish several papers in scientific journals:
a) the effect of the training on patient recall
b) the effect of the training on patient evaluation of communication, information, and involvement
c) the effect of the training on doctor adherence to principles of information provision
d) several other papers using qualitative methods, not about effects of the trial, but rather about how training affects the interaction in other ways.

Intention to publish date

01/02/2018

Participant level data

To be made available at a later date

Results - basic reporting

Results – Plain English Summary

Publication summary

Publication citation(s)

Contact(s)

Contact

Type
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Title
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Type
Hospital/treatment centre

Website

Privacy
Protected

Funder(s)

Funding Type
Not defined

Funder

Funder Name
EkstraStiftelsen Helse og Rehabilitering

Alternative Name(s)
Norwegian Foundation for Health and Rehabilitation ExtraStiftelsen

Funding Body Type
Private sector organisation

Funding Body Subtype
Foundation

Location

Norway

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Payment Method

Payment method
Online payment

Trusted funder

Invoice Details

Name

Institution

Address

City

State

Country

Zip

Email

Purchase order/ reference number

VAT number

Why did you choose ISRCTN to register your trial?
Previously registered a trial

BMJ Open

Training physicians in providing complex information to patients with multiple sclerosis; A randomised controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-049817.R1
Article Type:	Original research
Date Submitted by the Author:	07-Dec-2021
Complete List of Authors:	Nordfalk, Jenny; Akershus University Hospital, Department of Neurology; University of Oslo Faculty of Medicine, Institute of Clinical Medicine Holmøy, Trygve; Akershus University Hospital Neuroclinic, Department of Neurology; University of Oslo Faculty of Medicine, Institute of Clinical Medicine Thomas, O.; Akershus University Hospital, Health Services Research Unit HØKH Nylenna, Magne; Norwegian Institute of Public Health, Institute of Health and Society Gulbrandsen, Pal; University of Oslo Faculty of Medicine, Institute of Clinical Medicine; Akershus University Hospital, Health Services Research Unit HØKH
Primary Subject Heading:	Medical education and training
Secondary Subject Heading:	Neurology, Health services research, Cardiovascular medicine
Keywords:	Multiple sclerosis < NEUROLOGY, MEDICAL EDUCATION & TRAINING, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, EDUCATION & TRAINING (see Medical Education & Training)

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Training physicians in providing complex information to patients with multiple sclerosis; A randomised controlled trial.

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Word count: 3776

Keywords: Multiple Sclerosis, patient information, communication, randomised controlled trial

ABSTRACT

Objective: To evaluate the effect of a specific communication training for neurologists on how to provide complex information about treatment options to multiple sclerosis (MS)patients.

Design: Single-centre, single-blind, randomised controlled trial.

Setting: One university hospital in Norway.

Participants: Thirty-four early-stage Multiple Sclerosis (MS) patients.

Intervention: A three-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: The MS patients were instructed to imagine a disease development, and were randomized and blinded to meet a physician to receive information on escalation therapy, before or after the physician had participated in a three-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 (GLM) covariate was not significant (coefficient parameter 0.07 (SE 0.04, 95% confidence interval (CI) [-0.01; 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; -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, 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: ISRCTN 42739508

Strengths and limitations of this study:

- RCT design, adapted to health communication research
- Multiple sclerosis patients 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 (DMT) should be introduced initially, and which should be introduced as escalation therapy when relapse occurs[1] or if the patient initially presents with a very active disease.[2]

Informing MS patients 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.[3 4]

Medical information should ideally be provided in a way that enables patient autonomy and involvement in treatment decisions.[5] Patients desire tailored information.[6-8] The quality of communication is therefore crucial, if not clearly proven to influence the patients' ability to manage their disease,[6 7 9] at least to improve patient adherence.[10]

Several studies have shown that recall of medical information is suboptimal.[11-16] Cognitive impairments associated with MS make information processing more difficult.[17-19] Even in early-stage MS, subtle memory disturbance has been shown to be common.[20 21] Improvement of information recall among MS patients 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.[22 23] Intervention studies that link communication training of physicians to patient outcomes in general are rare,[24 25] 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 health care personnel.[23] Various oral communication strategies have been examined and found to improve patient recall in various ways; like repetition,[26 27] simplification of language, pauses, personal relevance,[27-29] and structuring.[27 30] One recent study has shown recall rate improvement by information structuring and categorization, but only for disadvantaged subgroups of a population.[31] Other studies have not showed such an effect, and the phenomena remain understudied in clinical populations.[32] 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.[33]

However, the interventions investigated have usually been long, and most often involved video-vignettes studies or analogue patients, i.e., 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, albeit in a fictitious setting, with a set of information provision strategies selected to tailor the needs of physicians working with MS patients. 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 visualized in figure 1.

Fig. 1 Study Design Overview. Result: Patient recall rate.

<PLEASE INSERT FIGURE 1 HERE>

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.[16 29 34-36] When designing this experiment, we therefore wanted to recruit real MS patients, 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.[37] 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.[38] The patients had to meet the following eligibility criteria to be asked for participation and included:

(a) being 18 years old or above;

(b) diagnosed with relapsing remitting MS (RR-MS) between 2009 and 2012;

(b) currently on no or first-line treatment;

(c) not yet exposed to a decision about choice of escalation treatment;

(d) 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 MS patients 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[39-41].

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 JCV antibody index of 0.8.[42-45], all framed as a journal exempt. Physicians were given approximately 20 minutes 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.[2 39]

Intervention

The intervention was a 3-hour communication training course, specifically focused on structured and patient-centered information provision, and targeted at physicians working in neurology. The course was developed and held by a professor specialized in health communication research with extensive experience in teaching medical students and physicians communication skills (PG). It was a condensed version of patient-centered 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, prioritizing 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).[26 27 31 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 MS patients, examples and practice cases aimed to illustrate treatment decision-making in MS were used. The course was provided in three sessions, for 5-6 physicians at a time, September 21-27, 2016.

Study procedures

A researcher not involved in the development and delivery of the training (JN) 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, JN performed the recall interview with the patient while the recording proceeded uninterrupted (Fig. 2). The recall interview guide was strict, with initial open questions, followed by a tailored part in which JN 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 August 16-September 15, 2016, post-intervention consultations took place October 3-November 3, 2016.

Fig. 2. Data Collection Procedure

<PLEASE INSERT FIGURE 2 HERE>

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.[40] 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 (JN, MN, PG) and demonstrated high inter-rater reliability (IRR) [50]. After establishment of the IRR, JN 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 standard deviation 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.

Randomization

An independent statistician performed the randomization 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. (Fig. 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. JN enrolled participants and assigned them blinded to either the control or the intervention group.

Statistical methods

We investigated the effect of the intervention on the recall rate, alongside various secondary outcomes. This was done with separate generalized 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 (MLE) inference was pursued, giving corresponding confidence intervals and p-values.

Ethics, privacy regulations, and pre-trial registration

The trial was registered in ISRCTN (www.isrctn.com) June 23, 2016, reg.: ISCRTN42739508.

The study was considered by The Regional Committee of Southeast Norway for Medical and Health Research Ethics. Reference # 2015/161. The committee decided that as this experiment was not covered by their definitions of medical or health research it was exempted from review. Participants received no compensation for their participation.

Patient and Public Involvement

An MS patient representative and a professor of medical ethics constituted an advisory group for the project.

RESULTS

Participants

All participants, patients and physicians, were included between April 12, 2016 and May 2, 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).

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					

Patient recruitment is shown in figure 3. Out of the 53 eligible MS patients we reached, 42 agreed to participate and provided informed consent (79%). They were randomised into two groups, each with 17 participants and 4 substitutes. 34 finally 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.

Fig. 3 CONSORT 2010 Participant Flow.

<PLEASE INSERT FIGURE 3 HERE>

Both pre- and post-intervention consultations lasted on average 21 minutes (range 8-29 minutes, median 20 minutes). 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 (GLM) covariate coefficient parameter 0.07 (SE 0.04, 95% confidence interval (CI) [-0.01; 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* secondary outcome with the intervention using a Poisson likelihood, we found the coefficient parameter -0.09 (SE 0.02, 95% CI [-0.13; -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; -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.[22 56] However, some papers suggested that courses of five 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 data set 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-h 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 prioritizing information tailored to the patient,[33] 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.[34 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 RCT design, are several. Real MS patients 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- and

post-intervention observations was similar. There was no attrition, so we had a complete set of data, and only one substitution among patients. The substitutes were also 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.

Secondly, the design of our study calls for caution in making causal inferences. As previous researchers have emphasized,[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. 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 mad e this analysis was, with the exception of JN, blinded to the intervention status of the transcripts from the consultations and recall interviews. Observer bias cannot be ruled out, although JN made efforts to ignore not being blind. Some results suggest the measurement is indeed valid; a) the measurement system was rigorously developed, yielding high inter-rater reliability,[66] b) there was no significant negative effect of increasing age within the age span 21 to 66 years on recall rate, and c) 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-hours course in providing complex information about treatment options to patients was sufficient to improve physicians' ability to prioritize 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

MS patients 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.

DECLARATIONS

Author contributions

P. Gulbrandsen: Conception and design, Methodology, Material preparation, Analysis and interpretation of data, Writing- Reviewing and Editing, Data curation.

T. Holmøy: Conception and design, Methodology, Material preparation, Analysis and interpretation of data, Writing- Reviewing and Editing.

O. Thomas: Formal statistical analysis, Analysis and interpretation of data, Reviewing and Editing.

M. Nylenna: Design, Methodology, Material preparation, Analysis and interpretation of data, Writing- Reviewing and Editing.

J.M. Nordfalk: Project administration, Investigation, Design, Methodology, Material preparation, Data collection, Analysis and interpretation of data, Writing- Original draft preparation, Reviewing and Editing, Data curation.

All authors read and approved the final manuscript.

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Ethics approval and consent to participate

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 gave their informed consent prior to their inclusion in the study. All participants were provided with information about the study orally and in writing 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.

Declaration of competing interests

All authors declare that they have no competing interest.

Data sharing

The data owner is Akershus University Hospital. Requests for anonymized data should be directed to co-author Professor Pål Gulbrandsen.

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FIGURE LEGENDS

Figure 1. Study Design Overview
Figure 2. Data Collection Procedure
Figure 3. CONSORT 2010 Participant Flow Diagram

SUPPLEMENTARY FILES

Registered study record: ISRCTN trial 42739508

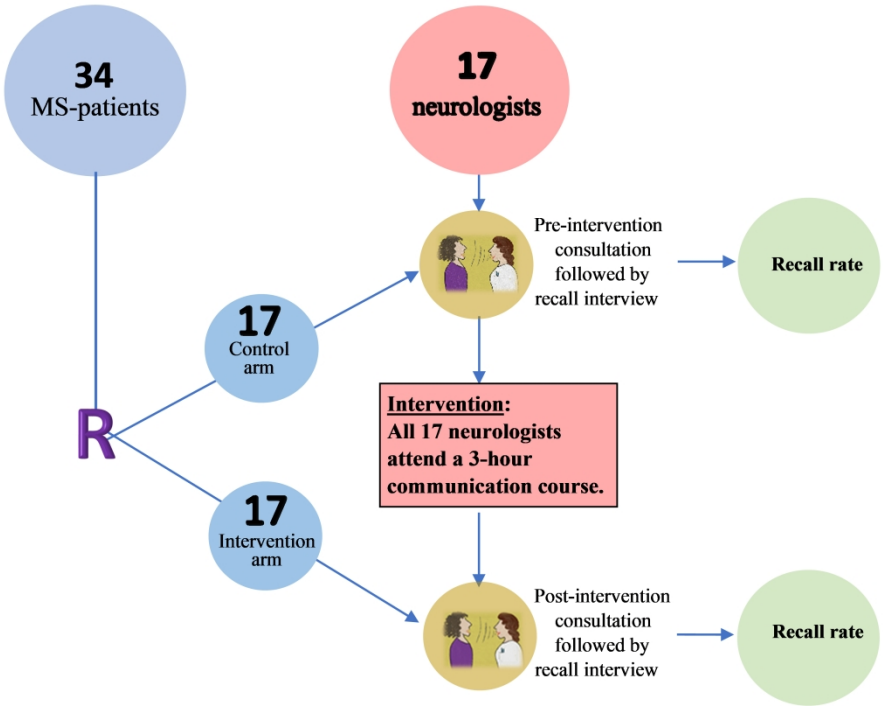

Figure 1. Study Design Overview

1015x720mm (95 x 95 DPI)

Figure 2. Data Collection Procedure

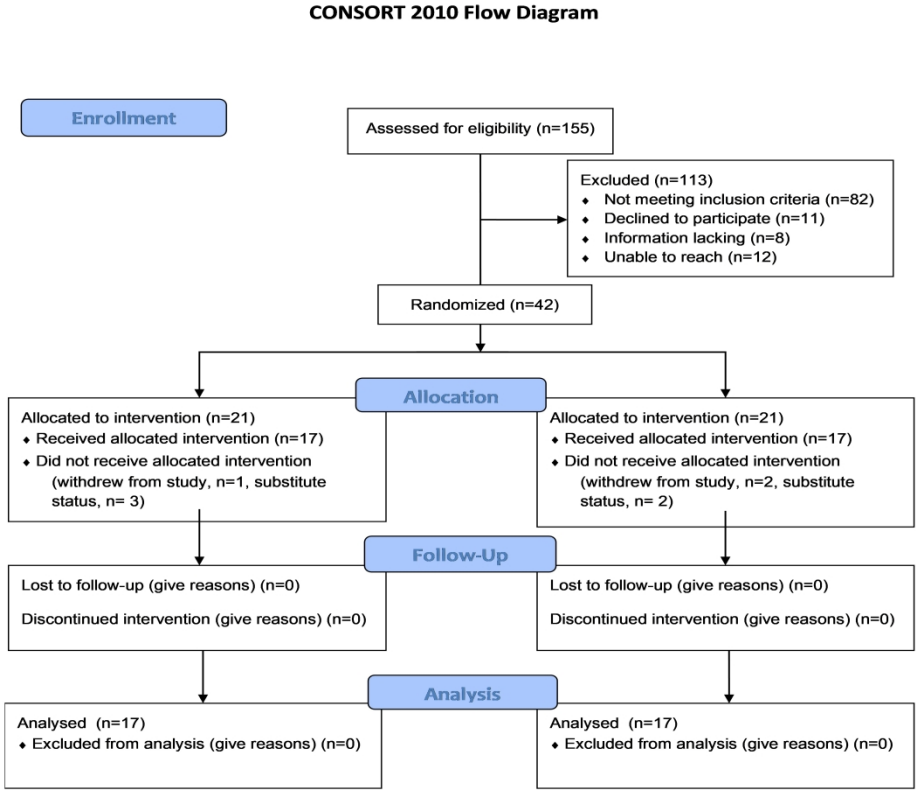

Figure 3. CONCORT 2010 Participant Flow Diagram

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
		Introduction	
Background and objectives	2a	Scientific background and explanation of rationale	3
	2b	Specific objectives or hypotheses	3-4
		Methods	
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	4
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

		assessing outcomes) and how	7
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	7
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	7
		Results	
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	8,9
	13b	For each group, losses and exclusions after randomisation, together with reasons	9
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	8
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	9
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	9
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	9
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
		Discussion	
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	10,11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	10-12
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	10-12
		Other information	
Registration	23	Registration number and name of trial registry	ISRCTN 42739508
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	EkstraStiftelsen Helse og Reha-bilitering (now Stiftelsen Dam) grant no. 7408.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

ISRCTN42739508

https://doi.org/10.1186/ISRCTN42739508

Improved involvement of multiple sclerosis patients in discussions about treatment

Condition category
Nervous System Diseases
Date applied
23/06/2016
Date assigned
24/06/2016
Last edited
15/01/2021
Prospective/Retrospective
Retrospectively registered
Overall trial status
Completed
Recruitment status
No longer recruiting
Publication status
Results overdue

Plain English Summary

Background and study aims:
Multiple sclerosis (MS) is one of the most common diseases of the central nervous system (brain and spinal cord). Healthy nerves are coated in a fatty casing (myelin sheath) which helps messages to travel quickly and smoothly along nerves. When a person is suffering from MS, the immune system, which normally helps to protect against infection, attacks the myelin sheath, stripping it from the nerves (demyelination). This demyelination means that messages cannot travel along the nerves effectively, causing a range of problems including loss of vision, problems with balance and coordination as well as fatigue (extreme tiredness), stress and mental health difficulties such as depression. Patients with MS often face difficult decisions about their choice of treatment. The reasons for this are several: the natural course of the disease is unpredictable but potentially serious, there are several new drugs available with different effects, side effects, and risks, and because of the drugs' novelty long-term effects are not well-known, while the disease itself is life-long usually spanning decades. It is hard, even for a doctor, to keep track of all the information available, and even experts will admit uncertainty about choice of treatment. Patient involvement in these situations is a difficult task. Patient involvement in decision-making requires information too be provided during medical encounters. Several studies indicate that doctors do not provide sufficiently structured, precise information and it is often characterized by use of jargon, and not adjusted to the patient's needs. This study aims to try out whether a rather simple training session for doctors leads to an improvement in these respects, in a way that helps patients to better recall the information they received.

Who can participate?
Adults with MS who are currently on their first drug treatment and doctors working in the Neurological department of Akershus University Hospital who regularly meet MS patients.

What does the study involve?
All participating doctors receive a three hour training session in groups of 5-8. The training session involves a brief introduction followed by learning about how best to provide patients with information. The rest of the session involves role playing, reflecting on the content of the session and providing feedback, before a brief summary at the end. Patients are randomly allocated to one of two groups. Those in the first group meet with the doctor for a consultation before they have attended the training session and those in the second group meet with the doctor after they have attended the training session. For both groups, the consultations are videotaped so that they can be reviewed by the research team to assess the information provided in the session. Patients are also interviewed before and immediately after the consultation in order to find out how much information the doctor gave them they are able to remember.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Akershus University Hospital (Norway)

When is the study starting and how long is it expected to run for?
April 2014 to December 2019

Who is funding the study?
Norwegian Foundation for Health and Rehabilitation, ExtraStiftelsen (Norway)

Who is the main contact?
Professor Pål Gulbrandsen
pal.gulbrandsen@medisin.uio.no

Trial website

Contact information

Type

Scientific

Primary contact

Prof Pål Gulbrandsen

ORCID ID

Contact details

HØKH Research Centre
Akershus University Hospital

Lørenskog
1475
Norway
95827288
pal.gulbrandsen@medisin.uio.no

Additional identifiers

EudraCT number

IRAS number

ClinicalTrials.gov number

Protocol/serial number

2015/FO7408

Study information

Scientific title

Enabling shared decision-making about treatment with multiple sclerosis patients: A preclinical intervention study

Acronym

Study hypothesis

A three hour course in how to provide information will improve MS patients' ability to recall information given by doctors.

Ethics approval

The Regional Committee for Medical and Health Research Ethics (Southeast Norway) decided that as this experiment is not medical or health research and therefore exempted from review. 24/03/2015, ref: 2015/161

Study design

Preclinical randomised parallel study

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Trial setting

Hospitals

Trial type

Other

Patient information sheet

Available in Norwegian by contacting the principal investigator:
pal.gulbrandsen@medisin.uio.no

Condition

Multiple sclerosis

Intervention

Participating patients are randomly allocated to meet a doctor before or after the doctor has been trained. One researcher observes the doctor-patient interaction and notes all information that is provided. The researcher interviews the patient directly after, first using open questions to elicit understanding and recall, followed by prompted, but not leading questions about information the doctor provided to elicit as accurate recall as possible. Both doctor-patient interaction and post-visit interview are videotaped, and independent coders that will not know if the interaction is pre or post intervention identify and decide whether patient recall of each information the doctor has given is sufficiently precise to represent the information given. Following these procedures the percentage of given information that is recalled, and whether there is a significant difference between patients in the pre-course and post-course arms of the study is calculated. In addition, a battery of questionnaires (MAPPIN'SDM, Collaborate, Four Habits Patient Questionnaire) will be used to map the patients' evaluation of communication, information provision, and involvement in decision-making.

The training session for doctors is led by an experienced teacher in clinical communication and lasts 3 hours and is run for groups of 5-8 doctors at a time. The training session involves being given a brief introduction about the 6 main steps of information provision:
1. Inducing a trusting atmosphere
2. Finding out what the patient knows
3. Prioritising which information to convey
4. Portioning information using micropauses
5. Rationing information when sensing that the patient feels unsafe
6. Checking what the patient has understood.

The rest of the session consists of role-plays, reflections, and feedback, and there is a brief summary round at the end.

Intervention type

Behavioural

Phase

Drug names

Primary outcome measure

The amount of information provided by the doctors that is recalled by the patients is measured using patient interviews immediately after the consultation.

Secondary outcome measures

1. Patient involvement is measured using:
1.1. Control preference scale (Degner et al), before and after consultation (patients and doctors)
1.2. MAPPIN' SDM (Kasper et al.) after the consultation (patients and doctors)
1.3. Collaborate (Elwyn et al.) after the consultation (patients only)
2. Communication and information quality is measured using the Four Habits Patient Questionnaire (patients)
3. Doctor communication self-efficacy is measured using Parle et al.'s self-efficacy questionnaire before and after the consultation and three months later
4. Adherence to information principles is measured through reviewing the video recordings of the sessions using the Four Habits Coding Scheme

Overall trial start date

01/04/2014

Overall trial end date

31/12/2019

Reason abandoned (if study stopped)

Eligibility

Participant inclusion criteria

Patients:
1. Patients with relapsing remitting MS
2. Currently use a first line drug
3. Not previously been exposed to the decision to begin with a second line drug
4. Aged 18 years and over

Doctors:
1. All doctors working in the Neurological department of Akershus University Hospital
2. Regularly meet multiple sclerosis patients

Participant type

Patient

Age group

Adult

Gender

Both

Target number of participants

Patients: 32 Doctors: 16

Participant exclusion criteria

No exclusion criteria.

Recruitment start date

01/05/2016

Recruitment end date

31/05/2016

Locations

Countries of recruitment

Norway

Trial participating centre

Akershus University Hospital
Post office box 1000
Lørenskog
1478
Norway

Sponsor information

Organisation

Akershus University Hospital

Sponsor details

Sykehusveien 25
Lørenskog
1478
Norway

Sponsor type

Hospital/treatment centre

Website

GRID

grid.411279.8

Funders

Funder type

Government

Funder name

Norwegian Foundation for Health and Rehabilitation, ExtraStiftelsen (EkstraStiftelsen Helse og Rehabilitering)

Alternative name(s)

Norwegian Foundation for Health and Rehabilitation, ExtraStiftelsen, Stiftelsen Dam & Dam Foundation

Funding Body Type

private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Norway

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan as of 15/01/2021:

Planned publication of papers in scientific journals:
The effect of the training on patient recall (soon to be submitted)
The effect of the training on patient evaluation of communication, information, and involvement (soon to be submitted)
The effect of the training on doctor adherence to principles of information provision (soon to be submitted)

———

Previous publication and dissemination plan:

Planned publication of several papers in scientific journals:
The effect of the training on patient recall
2. The effect of the training on patient evaluation of communication, information, and involvement
3. The effect of the training on doctor adherence to principles of information provision
4. Several other papers using qualitative methods, not about effects of the trial, but rather about how training affects the interaction in other ways

Intention to publish date

31/12/2021

Individual participant data (IPD) sharing statement
Participant level data

Data sharing statement to be made available at a later date

Trial outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
No data available in table					

Additional files

Editorial Notes

15/01/2021: The following changes were made to the trial record: 1. The publication and dissemination plan was changed. 2. The intention to publish date was changed from 31/12/2020 to 31/12/2021. 13/12/2017: Internal review. 11/12/2017: The overall trial end date was changed from 31/12/2016 to 31/12/2019. Intention to publish date was changed from 01/02/2018 to 31/12/2020.