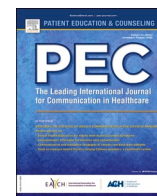




Contents lists available at ScienceDirect

Patient Education and Counseling

journal homepage: www.journals.elsevier.com/patient-education-and-counseling

Ready for SDM- evaluation of an interprofessional training module in shared decision making – A cluster randomized trial[☆]

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ARTICLE INFO

Keywords:

Shared decision-making
Inter-professional Education
Communication skills
Randomized controlled trial
Curriculum

ABSTRACT

Objective: Ready for SDM was developed in Norway as a comprehensive modularized curriculum for health care providers (HCP). The current study evaluated the efficacy of one of the modules, a 2-hour interprofessional SDM training designed to enhance SDM competencies.

Methods: A cluster randomized controlled trial was conducted with eight District Psychiatric Centres randomized to wait-list control (CG) or intervention group (IG). Participants and trainers were not blinded to their allocation. The IG received a 2-hour didactic and interactive training, using video examples. The primary outcome was the agreement between the participants' and an expert assessment of patient involvement in a video recorded consultation. The SDM-knowledge score was a secondary outcome.

Results: Compared to the CG (n = 65), the IG (n = 69) judged involvement behavior in a communication example more accurately (mean difference of weighted T, adjusted for age and gender: =−0.098, p = 0.028) and demonstrated better knowledge (mean difference =−0.58; p = 0.014). A sensitivity analysis entering a random effect for cluster turned out not significant.

Conclusion: The interprofessional group training can improve HCPs' SDM-competencies.

Practice implications: Addressing interprofessional teams using SDM communication training could supplement existing SDM training approaches. More research is needed to evaluate the training module's effects as a component of large-scale implementation of SDM.

1. Introduction

Shared decision-making (SDM) is a strongly recommended approach for health care providers (HCPs) to use when supporting people in making decisions about their health [1,2]. However, most HCPs lack SDM skills on entry into the workforce. Several studies and guidelines support the assumption that SDM is more likely to be applied if HCPs are

trained (2–4). An interprofessional approach including training of entire teams may be favorable to overcome known barriers to implementation of SDM in clinical practice (5, 6). Although an increasing number of studies evaluating effectiveness of SDM trainings have been recently published, there is insufficient evidence on best practices [3].

In addition, considerable heterogeneity of methods used for evaluation and teaching as well as learning objectives is making it difficult to

List of abbreviations: SDM, Shared decision-making; HCP, Health care providers; BCT, Behavior change techniques; IG, Intervention group; CG, Control group; DPC, District Psychiatric Centers; CRCT, Cluster randomized controlled trial.

* Trial registration: The ISRCTN (14184328) registry.

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<https://doi.org/10.1016/j.pec.2022.03.013>

Received 24 September 2021; Received in revised form 14 March 2022; Accepted 15 March 2022

Available online 17 March 2022

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identify the “active ingredients” [4–6] and to determine necessary duration and mode of delivery of training programs [5].

Several Norwegian university health-, social education-, and medical specialization programs, stimulating pronounced demands [7,8] for SDM trainings of different formats and durations.

To meet these demands, and in response to an obvious lack of SDM professional training in Norway, “Ready for SDM” (Norw. “Klar for samvalg”), a meta-curriculum was developed [1,5,9–13]. Ready for SDM comprises several SDM training modules using both classroom and online format, providing guidance for tailoring SDM training to the different contexts and needs of HCPs. The framework is based on MAPPINSDM (Multifocal Approach to the Sharing in SDM) as its underpinning concept of SDM quality [14,15]. MAPPINSDM defines the chronological steps of an SDM approach and provides detailed descriptions of several levels of performance for each quality indicator [14, 15]. Using a generic pedagogic approach [12], the Ready for SDM meta-curriculum also relies on a set of behavior change techniques (BCTs) to address the SDM-behaviors of HCPs in consultations [6]. BCTs are defined as “an observable, replicable, and irreducible component of an intervention designed to alter or redirect causal processes that regulate behavior; that is, a technique is proposed to be an ‘active ingredient’ (p. 23)” [6]. In 2013, Michie and colleagues proposed an evidence-based taxonomy of 93 hierarchically clustered BCTs with the aim of building an international consensus for reporting behavior change interventions [6]. The key pedagogical aim for several of the modules in the meta-curriculum is to stimulate the participants self-observation and self-reflection by acquiring SDM observation skills. More specific, by incorporating the concept of SDM quality participants are encouraged to recognize and discover their own skills leading to continued learning in clinical practice also after the training [10,11].

Amongst the modules in the meta-curriculum, SDM INTERPROF, a 2-hour classroom educational course for interprofessional groups is one of the most requested low threshold offers. The module has been pre-tested and shown to be easy to understand, acceptable, relevant and likely to improve knowledge about SDM [12]. To better fit the needs of an inter-professional approach, it has been adapted with additional training videos from various healthcare contexts allowing for adjustment of the training to groups of HCPs from varying health domains [12,13]. However, SDM INTERPROF has not yet been evaluated to determine its effect on HCPs basic knowledge and competencies related to SDM.

1.1. Study aim

The overall aim is to evaluate whether Ready for SDM INTERPROF is improving SDM-related communication competencies of HCPs in interprofessional health care teams. The latter were operationalized as the ability to judge decision-making communication in terms of SDM from an observer perspective and SDM knowledge. Although the module is developed to address a much broader target population regardless of the specific health domain, mental health was chosen as an important and relevant example domain.

2. Methods

2.1. Study design

Using a cluster randomized research design, entire departments (see Fig. 1) were allocated to an intervention- (IG) or wait-list control group (CG). CRCT was chosen to avoid contamination effects. The study was approved by the Ethics Committee (REK) of South-Eastern Norway Regional Health Authority (2017/82 C) and the local ethics committee at the University Hospital in Northern Norway (UNN), (2017/1461). We followed the extended CONSORT reporting statement for cluster randomized controlled trials (CRCT) [16]. In addition we used the Template for Intervention Description and Replication (TIDieR) checklist to structure the detailed description of the training intervention [17].

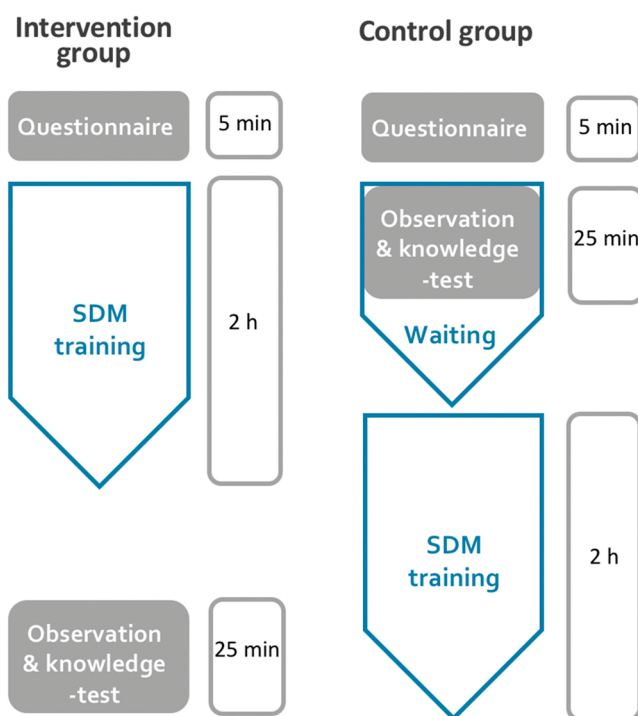


Fig. 1. Study design. The figure demonstrates how proceedings are organized to allow for a waiting control group design.

The trial protocol was registered in the Current Controlled Trials register (ISRCTN 14184328).

2.2. Settings and recruitment

The clusters were each of the eight community mental health centers, in Norway referred to as District Psychiatric Centers (DPCs). DPCs are organized as part of the specialist healthcare under four regional health authorities. In cooperation with primary mental healthcare and hospital-based mental health services, DPCs are providing a broad range of outpatient mental health care. The trial was appended to ongoing training activities in the Western (6 DPCs) and the South-Eastern Norway Regional Health Authorities (2 DPCs) which are part of a comprehensive strategy to implement patient involvement in specialist medical health care. Conveniently, clusters were recruited when requests for SDM training were received at the regional health authorities. Departments interested in SDM training were asked to accept accompanying evaluation of the training as part of the CRCT.

2.3. Participants

Healthcare providers were eligible if working in clinical functions in the respective centers and willing and able to provide informed consent including mandatory attendance during the entire course. Participants were not eligible if they were not working in a clinical setting (e.g., administrative functions or being employed by others than the respective institutions).

2.4. Randomization

Once consent was provided by the DPCs, randomization of the clusters was conducted after enrollment of all the DPCs (done by SK), by an independent person using simple randomization as method (allocation concealment) [18]. Due to the nature of the training intervention and assessment before the training course (CG) or after the training course (IG), participants could not fully be blinded regarding their

allocation. Trainers who provided the intervention were not blinded either.

2.5. Intervention

The Ready for SDM INTERPROF module [12] is a 2-hour interprofessional SDM training for HCPs targeting entire departments, wards or teams. Using “the Ready for SDM meta-curriculum” targeting behavior change [6,10,12], “blended learning” and adult learning approaches [19] the training includes a presentation, group discussions, video recordings, and interactive exercises. Each single component of the module’s curriculum is referring to a specific BCT (see Table 1) [6,13,20]. By providing an introduction to the topic SDM and related basics, the module is intended to function as a door opener to implementation of patient involvement into specialists’ health care practices.

More specific, the first hour of the training was a basic introduction to SDM (lecture and exercises) building positive attitudes and improving knowledge about SDM). The second hour involved participants watching a pre-recorded training video of a 12-min interprofessional consultation showing a consultation between a patient, a psychiatrist and a psychiatric nurse considering options for the treatment of depression. To build core competences specific for SDM communication skills [11,12], participants were asked to assess indicators of patient involvement in decision making on a 11-items coding sheet. The sheet is a modified version of the MAPPIN’SDM dyadic observer scale [14,15]. These modifications involved removing questions addressing structural characters of the consultation that were not relevant (e.g. time of the decision)”. The exercise was then used as stimulation for a group discussion before a final fictitious debriefing was presented by the trainers. The debrief was also based on a MAPPIN’SDM analysis and addressed the characters in the given video recording. The slides presented during the course, the exercises, a transcript from the consultation and a detailed curriculum are available from the corresponding author.

Table 1
Learning objectives and behavior change techniques.

| Learning objectives | Behavior change techniques |
|--|---|
| Knowledge on background and rationale of SDM and risk communication. | <ul style="list-style-type: none"> • Goal setting (behavior) (1.1) • Use of a credible source (9.1) • Problem solving (1.1) • Guidance of action planning (1.4) • Information about social and environmental consequences (5.3) • Information about others’ approval (6.3) • Information about health consequences (5.1) • Tailoring (Agbadjé 2020) * |
| Skills to structure an SDM process using “6 steps to SDM” | <ul style="list-style-type: none"> • Instruction on how to perform the behavior (4.1) • Problem solving (1.1) • Adding objects to the environment (12.5) • Restructuring the social environment (12.2) |
| Develop self-appraisal skills using quality criteria from the MAPPIN’SDM | <ul style="list-style-type: none"> • Demonstration of the behavior (6.1) • Social comparison (6.2) • Information about others approval (6.3) • Feedback on behavior (2.2) • Feedback on outcome(s) of the behavior (2.7) • Problem solving (1.1) |

This table presents learning objectives and behavior change techniques (BCT) used in the training. Numbers added in brackets refer the Michie’s BCT taxonomy (2013) or additional BCTs proposed by Agbadjé et al. [57] * . SDM, shared decision making. BCTs, Behavior change techniques.

2.6. Procedures and data collection

Before randomization, the management of the participating department / institution agreed orally or via email to participate in the training as part of a research study. Additionally, the participating HCPs signed a consent form before training and completing the questionnaires.

The intervention was delivered by SK and JK acting as an interprofessional team for all clusters. SK is a registered nurse with a master’s degree in Health and Empowerment and is a PhD student focused on SDM training, as well as a special advisor for SDM at the South-Eastern Norway Regional Health authority. JK is a psychologist, professor and communications researcher. Both trainers have extensive experience in conducting SDM trainings. The course was provided following a protocol to ensure standardized delivery of the training at all sites.

After administering a demographic questionnaire, the IG started with the SDM training module. Immediately after completion of the training module, primary and secondary endpoints were assessed (see Fig. 1).

The CG was placed on a wait-list to receive the SDM training at the end of the trial (Fig. 1). Although the CG was not blinded to the intervention, they were not explicitly told about the waiting condition and likely did not aware about their allocation in the CG. The wait for training did not last long and the observation- and the knowledge test were gathered in the waiting time before the training was provided.

2.7. Measurement

2.7.1. Participant characteristics

The baseline questionnaire included questions on gender, age, profession, position, years of clinical practice, previous SDM training, decisions recently made with patients, attitude towards patient involvement and perceived SDM skills.

2.7.2. Outcomes

Primary outcome: The SDM specific communication competencies were operationalized as the ability to judge decision-making communication in terms of SDM from an observer perspective. Although not reflecting skill-level regarding active communication, the extent to which a HCP is evaluating observed communication accurately was determined to be a reasonable proxy for SDM communication competencies and has been used in previous studies [13,21]. It measured whether participants were able to discriminate varying levels of SDM performance. To ascertain this ability, participants were exposed to a video of a decision consultation recorded in the respective clinical domain and asked to score their observations using an observer sheet, which was taken from the MAPPIN’SDM inventory [14,15]. MAPPIN’SDM provides five SDM assessment scales for observers and self-assessment covering both varying perspectives (patient, physician, observer) and foci (patient, physician, dyad) with an identical set of 11 quality indicators, each scoring from ‘0’ (“The behavior is not performed”) to ‘4’ (“The behavior is performed to an excellent standard”). The observer scale focused on measuring the communication performance of the patient-HCP dyad [14,15]. The 10-minute test video showed a real consultation of a psychiatrist consulting a patient diagnosed with bipolar disorder. The camera focused on the clinician, while the patient is audibly present. The consultation is about making a decision on increasing the current dose of medication to better stabilise mood fluctuations. This consultation recording was considered suitable for the purpose of the current study because it is showing an average SDM performance applied to a frequent medical problem. The reference assessment of the test video-recorded consultation was a rating established by two experts in MAPPIN’SDM, with previous good inter-rater reliability before the study started [15].

Secondary outcome: SDM related competencies were also assessed in terms of basic knowledge about SDM. Therefore, a five-item multiple choice knowledge test previously used in similar studies [9,21] and in other modules within the Ready for SDM framework [12,13] was used.

The items cover the following subjects: Definition of SDM, indication and contra indication, prerequisites of informed choices and reliable sources of information about effects of medical interventions [12]. Each item provides five alternative answers, four of which distractors and one correct answer. The original set of the questions was previously published elsewhere [13].

2.8. Sample size

The necessary size of in total 158 participants (control group: N = 79; Intervention group: N = 79) in the study sample was calculated using G*Power [22] based on distribution data (mean values and SDs) of a previous unpublished study. It was chosen to allow for detection of a difference of 0.15 weighted T coefficient in the primary outcome (accuracy of judgements on the MAPPIN'SDM observer scale) with a power of 0.95, two-tailed analysis, and a tolerated $\alpha = 0.05$. The calculation is considering a design effect of 1.25 based on an ICC of 0.07, which was taken from a similar study [23] and can compensate for an estimated drop-out rate of 25%.

2.9. Statistical analyses

Data were analyzed using SPSS version 26.0 (IBM corporation, USA). Individual baseline data of the participants were described as frequencies, percentages and if appropriate means and SDs.

Agreement rates between the reference and each individual assessment was expressed using the weighted T coefficient applied to the MAPPIN'SDM mean score [24]. In case of missing values, interpolation was used to ascertain the mean score. Additionally, agreement levels were calculated on item level (Table 3). T is a Cohens kappa, modified according to Maxwell [25] that uses theoretical assumptions rather than empirical frequencies to estimate the expected marginal distributions. Agreements were downgraded from full agreement (=1), over almost (1 Likert step = 0.75), moderate (2 Likert steps = 0.25), low (3 Likert steps = 0.1) to no agreement (4 Likert steps = 0). Coefficients are considered moderate between 0.40 and 0.60, strong higher than 0.60, and excellent higher than 0.80 [26].

Answers from the five-item knowledge tests were analyzed dichotomously as either "correct" or "incorrect" according to the test manual [9,21]. A mean score was calculated over the five multiple choice items. Missing values were counted as incorrect.

Possible differences between the intervention and control groups regarding primary and secondary outcomes were modelled using mixed models. There were no differences between the intervention and control group regarding any baseline characteristics, however all the models were adjusted for age and gender as it is customary in clinical research. Firstly, age, gender and group (intervention vs controls) were entered as fixed effects. The results are expressed as the estimated mean differences with 95% confidence intervals (CI). To compensate for the limited sample size, all the presented CI are derived using bootstrapping with 10,000 repetitions (bca – bias controlled acceleration method). We assumed very low between centers variability as we considered them very similar, however we conducted an additional sensitivity analyses to adjust for the effect of centers entered as random effects.

3. Results

3.1. Participant flow

3.1.1. Recruitment

Cluster level recruitment of DPCs was carried out November 2017 to April 2018. Intervention and control group were carried out between April and June 2018 (See Fig. 2).

3.1.2. Sample characteristics

Within eight study centres, a total of 153 health professionals

Table 2
Demographics and attitudes at time of inclusion.

| Participants | | IG N = 69 (%) | CG N = 65 (%) | |
|---|--|------------------|---------------------|-----------|
| Gender | Female | 50 (72.5) | 46 (70.8) | |
| | Male | 18 (26.1) | 18 (27.7) | |
| | Missing | 1 (1.4) | 1 (1.5) | |
| Age, years | < 30 | 6 (8.7) | 14 (21.5) | |
| | 30–50 years | 36 (52.2) | 20 (30.8) | |
| | > 50 years | 25 (36.2) | 30 (46.2) | |
| Profession | No respons | 2 (2.9) | 1 (1.5) | |
| | Nursing students | 1 (1.4) | 4 (6.2) | |
| | Registered Nurses | 19 (27.5) | 22 (33.8) | |
| | Other healthcare students | 1 (1.4) | 1 (1.5) | |
| | Physiotherapists | 2 (2.9) | 0 (0) | |
| | Occupational Therapists | 1 (1.4) | 0 (0) | |
| | Psychologist student | 1 (1.4) | 0 (0) | |
| | Psychologists on varying specialization levels | 13 (18.8) | 14 (21.5) | |
| | Physicians on varying specialization levels | 12 (17.3) | 14 (21.6) | |
| | Social worker | 6 (8.7) | 2 (3.1) | |
| | Social Educators | 6 (8.7) | 3 (4.6) | |
| | Music therapist | 0 (0) | 2 (3.1) | |
| | Consumer representative | 2 (2.9) | 1 (1.5) | |
| Position | Advisor/ leader | 0 (0) | 2 (3.1) | |
| | Others | 3 (4.3) | 0 (0) | |
| | Missing | 1 (1.4) | 0 (0) | |
| | Clinical practice | 58 (87.9) | 52 (83.9) | |
| | Management | 7 (10.6) | 10 (16.1) | |
| | Research and Professional development/teaching | 1 (1.5) | 0 (0) | |
| | Missing | 3 (4.3) | 3 (4.6) | |
| | Reported mixed positions | 3 (4.2) | 3 (4.6) | |
| | Years of clinical practice | < 1 | 2 (2.9) | 5 (7.7) |
| | | 1–5 | 13 (18.8) | 16 (24.6) |
| | | 6–15 | 24 (34.8) | 13 (20) |
| | | > 15 | 29 (42) | 30 (46.2) |
| | | Missing | 1 (1.5) | 1 (1.5) |
| Previous SDM training | Yes | 10 (14.4) | 12 (18.5) | |
| | No | 58 (84.1) | 53 (81.5) | |
| | Missing | 1 (1.5) | 0 (0) | |
| Medical decision taken with a patient the recent three weeks | Yes | 47 (68.1) | 49 (75.4) | |
| | No | 21 (30.4) | 16 (24.6) | |
| | Missing | 1 (1.5) | 0 (0) | |
| | If yes: range /mean (SD) | 1–20 / 7.1 (6.1) | 1–30 / 6.3 (6.5) | |
| | Mention of SDM relevant decisions (free text) | 43 (62) | 42 (65) | |
| Attitudes towards patient involvement | Very little/little in favour of | 1 (1.5) | 3 (4.6) | |
| | Neutral / don't know | 4 (5.9) | 4 (6.2) | |
| | Much very much / in favour of | 61 (89.7) | 58 (89.2) | |
| | Missing | 2 (2.9) | 0 (0.0) | |
| Perceived SDM skills | Low or very low | 3 (4.4) | 4 (6.1) | |
| | Undecided / don't know | 31 (45.6) | 30 (46.2) | |
| | High or very high | 32 (47.1) | 31 (47.7) | |
| | Missing | 2 (2.9) | 0 (0) | |

participated in the training and of these, 134 completed the questionnaires and were included in the CRCT (see Fig. 2). Typical participants were female (72%), over 30 years of age, and over 15 years of work experience (42%) (Table 2). Most of the participants were active decision-makers and recalled SDM relevant decisions which they had taken within three weeks before the training intervention. Examples of actual SDM decisions were: considering changing medications, deciding between different types of treatments for ADHD, deciding treatment for depression, and deciding different forms of therapy mentioned. Prior to training, participants reported positive attitudes regarding patient involvement, 47% reported good SDM skills, and 53% reported being unsure or holding limited SDM skills. The majority (IG 84%, CG 81%)

Table 3
Group differences regarding agreement with the reference standard on item level.

| Item | Content | Weighted T CG | Weighted T IG | P value |
|------|--|---------------|---------------|---------|
| 1 | Clinician & patient agree on a concrete problem as one that requires a decision-making process. | ,28 | ,56 | .006 |
| 2 | Clinician & patient discuss that there is more than one way to deal with the concrete problem. | ,44 | ,55 | .255 |
| 3a | Clinician & patient structure the discussion of the options in a way that is easy to understand and easy to remember. | ,21 | ,40 | .091 |
| 3b | Clinician & patient weigh up the pros and cons of the different options (if applicable, also the pros and cons of 'doing nothing'). | ,03 | ,19 | .148 |
| 3c | Clinician & patient consider the criteria of evidence-based patient information (presentation, sources, level of evidence). | -,05 | ,04 | .493 |
| 4 | Clinician & patient discuss the patients' expectations (ideas) and concerns (fears) about how to manage the concrete problem. | ,36 | ,55 | .045 |
| 5 | Clinician & patient open the decision stage leading to the selection of an option (If applicable, deferment is a possible decision). | ,39 | ,29 | .434 |
| 6 | Clinician & patient discuss plans for how to proceed (e.g. steps for implementing the decision, review of decision or of deferment). | ,58 | ,57 | .963 |
| 7 | Clinician & patient choose an approach to exchanging information (setting, media, time frame). | -,16 | -,20 | .755 |
| 8 | Clinician & patient clarify whether the patient understood the information given by the clinician correctly. | -,19 | -,01 | .175 |
| 9 | Clinician & patient clarify whether the clinician has understood the patients' viewpoint correctly. | ,41 | ,39 | .858 |

The table presents agreement levels on the MAPPIN'SDM observer scale calculated as T-coefficients between participants and an expert standard. The Ts are displayed on item level and separately for study groups, and a p-value provided for comparison.

had no previous formal SDM training. Fig. 2.

3.2. Primary endpoint

Analysis of the primary endpoint was based on 58 participants from the IG and 65 from the CG. The IG demonstrated higher SDM competencies compared to the CG. The mean difference of weighted T between the intervention and control group (adjusted for age and gender) was -0.098 , 95% CI $[-0.184; -0.011]$, $p = 0.028$. Although significant, the effect was low in size (0,2) and the mean levels of agreement on item level varied widely. In some items, height of agreement was comparable with trained raters even in the CG (Table 3). The advantage of the IG participants' appraisal compared to the CG refers to more accurate ratings of three items (1, 3a, 4, Table 3) while performance on rating the other eight items did not seem affected by the training (Table 3). Calculation of the ICC based on data for the primary endpoint in this study revealed a value of 0.064.

Sensitivity analysis: In a mixed model adjusted for age, gender, group and with cluster entered as a random effect, the between group difference was very similar to the point estimate from the model without a random cluster effect. However, the difference did not reach the level of

statistical significance. Mean difference = -0.090 , 95%CI $[-0.24; 0.061]$.

3.3. Secondary endpoint

Analysis of the secondary endpoint was based on 60 participants from the IG (9 missing for analysis) and 64 from the CG (1 missing for analysis). The IG demonstrated higher knowledge about SDM. In a mixed model adjusted for age, gender and group, there was a statistically significant difference between intervention and control group. Mean difference = -0.584 ; 95%CI $[-1.045; -1.123]$, $p = 0.014$. Although significant, the effect was low in size (0.23).

3.3.1. Sensitivity analysis

In a mixed model adjusted for age, gender, group and with cluster entered as a random effect, the between group difference was very similar to the point estimate from the model without a random cluster effect. However, the difference did not reach the level of statistical significance. Mean difference = -0.543 , 95%CI $[-1.400; 0.313]$, $p = 0.169$.

4. Discussion and conclusion

4.1. Discussion

Our study evaluated a tailored 2-hour interprofessional group-based training intervention in a cluster-randomized trial and showed improved HCPCs' SDM- competencies in observation and appraisal of communication examples in terms of SDM and relevant basic SDM-knowledge. A majority of participants remembered decisions requiring an SDM approach from their own clinical practice, indicating relevance of the topic. Our findings lead us to the following points of discussion.

Our study has a few limitations. First, the effect on competencies in judging communication was smaller than intended and is referring to two to three of in total 11 criteria only. Although statistically significant, this result is slightly dampening expectations towards the potential impact of this kind of interventions. The study was powered to reveal a difference of 0.15 between the groups, and to compensate possible dropouts and even an increased variability between the clusters, however power calculation did not adjust for the additional random effect of cluster. When using mixed models with fixed and random effects, one need to compute a range of parameters thus this method is quite computationally demanding and requires a large data set. However, the point estimates from sensitivity analyses for both the main and secondary outcomes are very similar to those derived from models without the random effect of the cluster. Also, the differences on the level of single criteria (Table 3) provide a meaningful pattern in line with the learning goals and might even expand after implementation of the new skills in practice.

Second, due to the fact that the data collection was performed within the same setting and administrated by the same people, blinding of the trainers and the participants was not possible. However, the outcomes were objective measures and less likely to be influenced by the lack of blinding. Third, analyses of the CRCT, on the level of clusters might have gained more robust results, however, on the other hand neglected individual variability within the clusters. Moreover, variation of size between the clusters would have meant a disadvantage of cluster level analysis [27,28]. Fourth, the primary and secondary endpoints were assessed either at the beginning of the training session or at the end. Due to varying preparation, the assessment of the outcomes might have caused information bias on both sides (trainers and participants). Through developing a deeper understanding of the meaning of the task required by the assessment of the endpoints, and encouragement by the trainers, participants in the IG might have become more motivated to deliver a good performance, implying a potential overestimation of the real effect by our study results. We do, however, believe the impact of

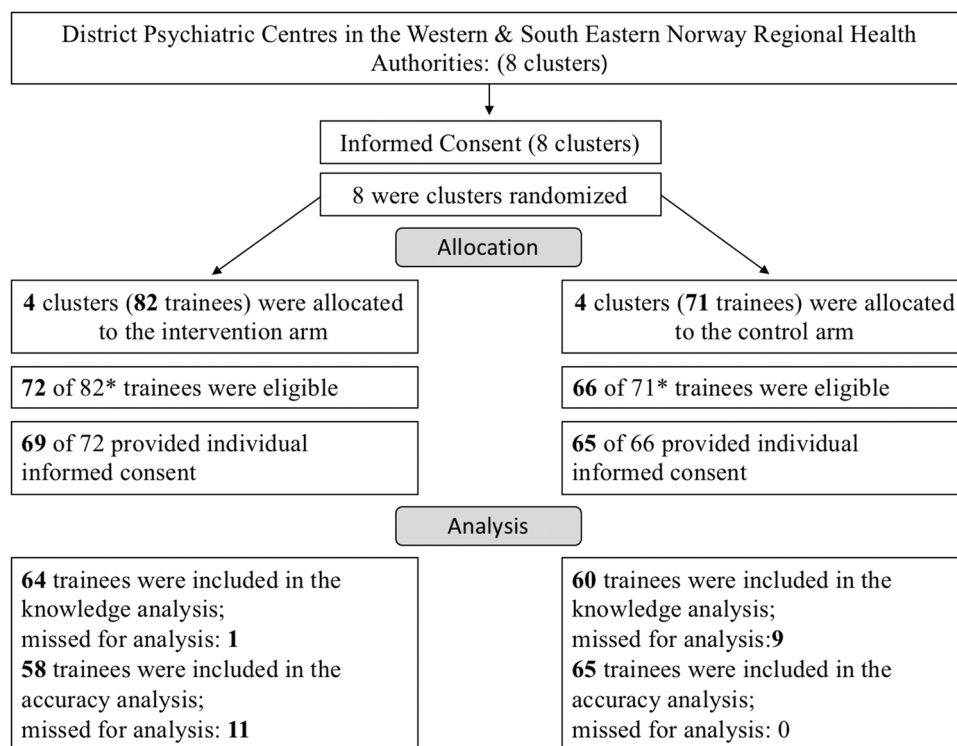


Fig. 2. Participant flow. Fig. 2: Flow diagram of the Ready for SDM INTERPROF study. Eight clusters were randomized. *Not eligible due to partial absence from the training.

this bias was minimal. Fifth, the unequal distribution of dropouts between the study groups (0 in CG, 11 in IG) begs the question of an attrition bias. Dropouts might have impacted the average level of communication competence. This can be true in both directions. With regard to our observations during the study we do however strongly believe that the only reason for this inequality was the fact that participants had to leave the training session due to time schedule issues; this, however, only interfered with the assessment of endpoints in the IG.

Although the trial was conducted in only one healthcare domain, the mental health care services, we anticipate that the results are transferable to other healthcare domains given the standardized training intervention. The only aspect limited to mental health was the educational video examples and this allowed us to use the identical course content across all clusters. This selection was also a good choice as SDM applied to mental health is an understudied domain [29] and few studies evaluated training programs within this health domain [5,30–33]. Furthermore, patients with mental health conditions prefer active roles in making decisions about their own health [34]. SDM might be of particular relevance in mental health contexts [35], as mental disorders often are long-lasting, or even chronic, requiring several decisions over time and patient preferences might often differ from HCPs' preferences [36]. In Norway, hospital trusts are required to invite patients with mental health problems to participate in making choices, including the option of using no medication for psychosis [37]. These ongoing political and professional discussions are reflected by the design of two patient decision aids for bipolar and psychosis disorders to help patients making specific and deliberate choices among healthcare options, concurrently with our own development [38–40]. Norwegian HCPs working in district psychiatric centers have been shown to hold inconsistent definitions of SDM and to be in need for theoretical and practical training [41].

To increase the scope and quality of patient involvement in decisions requires a multifaced implementation strategy including interventions targeting patients, HCPs, and organizational levels [3,42–44]. This could include providing highly effective targeted in-situ training to

physicians [11], modules addressing other HCPs such as decision nurses [45,46] and approaches for interprofessional groups [47] such as the current. It is also suggested that an interprofessional approach to training whole departments, units, or teams will be more useful than training individuals from various teams [43]. Further research is required following our study to determine if the interprofessional training prepared HCPs in mental health services to increase delivery of SDM within clinical practice.

The training, using a combination of BCTs, was designed to improve motivation, attitudes and SDM behaviors and create a more sustainable learning experience [13]. Being able to refer to the taxonomy of evidence based BCTs when justifying our set of didactic strategies also makes the intervention transparent and transferable from a methodological point of view [13]. The core pedagogic element within the training is stimulation of self-appraisal by applying the quality criteria from the MAPPIN'SDM [14,15] to domain specific videotaped consultations. Similar methods, e.g., using analysis of video-recordings of real or simulated patient consultation have also been used in other SDM training programs [11,30,48,49]. According to several authors, [10,48,50] physicians consider the latter exciting, interesting, helpful for self-reflection and one of the most beneficial training components. Analyses of observed communication skills have also been used as an outcome measure in several other studies [11,31,51–53]. To the best of our knowledge, no studies evaluating communication competencies in general have used the trainees' observation skills as an operationalization of SDM specific communication competencies.

Kirkpatrick's four-level model provides an important classification of outcomes for measuring training (reaction, learning, behavior, and results) [4]. Our research has previously assessed participants' reactions and the module was proven acceptable and feasible [12]. This current study has demonstrated learning of SDM knowledge and evidence of behaviors learned. However, we have not measured the effects of the SDM training on patient outcomes and this is consistent with findings from other studies [5,30]. The logical succession of the four steps to gain sound evaluation results in the efficacy trials is justified by the theory of

planned behavior according to which positive attitude, acquirement of relevant knowledge and improvement of skills will determine HCPs behavioral intentions, and thus behavior change [54].

Further studies will evaluate the impact of Ready for SDM measures on patient relevant outcomes and investigate the training strategies as complex interventions composed of several trainings and additional strategies.

5. Conclusion

This study seems to show that the 2-hour SDM INTERPROF training can improve health care providers' SDM competencies by increasing their knowledge and developing their skills in judging patient involvement in decision making in terms of SDM. There is a need for additional knowledge about the training effects, with particular focus on patient outcomes and the role of the training module in the context of a comprehensive implementation strategy.

5.1. Practice implications

The interprofessional SDM module evaluated in the current study is the first module of its kind in Norway. The current study is considered having reasonable external validity as it was conducted within the clinic and within the continuous training of HCPs. However, replication of our study with a more diverse sample, but still using domain specific video examples would be important to evaluate for external validity.

Within the spectrum of measures needed for sustainable implementation of SDM, this module is intended to work as a facilitator, establishing the foundations for effective application of other strategies. The Ready for SDM meta curriculum, to which this module belongs, is providing complementary modules which are suggested to be combined in order to further enhance the impact of SDM implementation efforts. In particular, more comprehensive training for whole departments [55], “decision coaching” addressing nurses [56] and/or individual feedback [10,11] should be used. The scaling up of training in Norwegian hospital trusts using the interprofessional training module investigated in this trial is facilitated by a corresponding newly developed train the trainer program [1,13].

Funding

The project was funded by the Northern Norway Regional Health Authority (DA-factory HST1246-15) and the South-Eastern Norway Regional Health Authority and was undertaken as part of the project “Decision aid factory” (DAfactory), “Klar for Samvalg” (Ready for SDM).

CRediT authorship contribution statement

Simone Kienlin: Conceptualization, Methodology, Validation, Formal analysis, Investigation, Data curation, Writing – original draft, Writing – review & editing, Funding acquisition, Visualization, Project administration, **Dawn Stacey:** Conceptualization, Methodology, Validation, Supervision, Writing – review & editing, **Kari Nytrøen:** Conceptualization, Methodology, Supervision, Writing – review & editing, **Alexander Grafe:** Formal analysis, Writing – review & editing, **Jürgen Kasper:** Methodology, Validation, Investigation, Formal analysis, Writing – original draft, Supervision, Visualization, Writing – review & editing, Funding acquisition.

Declaration of Competing Interests

We confirm that this work is original and has not been published, nor is it currently under consideration for publication elsewhere. We confirm that all authors have contributed significantly, have approved the manuscript for submission, and confirm not to have any competing interests.

Data Availability

The data that support the findings of this study are available on request from the corresponding author (SK).

Acknowledgements

We would like to acknowledge all the healthcare providers who participated in the study. Last but not least, without the health professionals who willingly provided their videos of consultations for use within Ready for SDM trainings, this study would not have been possible to carry out. We also want to thank Milada Cvcancarova Småstuen very much for supporting us as a biostatistician in conducting statistical analyses.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at [doi:10.1016/j.pec.2022.03.013](https://doi.org/10.1016/j.pec.2022.03.013).

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