ISRCTN14184328 https://doi.org/10.1186/ISRCTN14184328

Ready for SDM - evaluation of a multidisciplinary training module in Shared Decision Making

Submission date
17/04/2018

Recruitment status
No longer recruiting

Registration date
09/05/2018

Overall study status
Completed

Last Edited
10/06/2024

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In response to an obvious lack of professional training about shared decision making (SDM) in Norway, a draft of the “Ready for SDM” program was developed based on a proven effective German module (doktormitSDM). Two applications (Norw. “Klar for samvalg”) (M1 / M2) have recently been tested in a pilot study, indicating a need for better adaptation to various health professions and inter-professional learning. This study aims at testing the effectiveness of the revised M2 regarding improvement of SDM-related evaluation competences.

Who can participate?
6-10 District Psychiatric Centers recruited from the South – Eastern Norway Regional Health Authority and the Western Norway Regional Health Authority

What does the study involve?
Participating District Psychiatric Centers are randomly allocated to either an intervention or a waiting control group. After a demographic questionnaire, the intervention group starts with the introduction module A, followed by B: SDM in-depth, and C: interactive training. After completion of modules A-C the intervention group participants are assessed, and the control group participants are assessed as long as the group is untrained (has not yet received the training module). After the study, the training module is also conducted for participants in the control group.

What are the possible benefits and risks of participating?
Participants taking part in this study may benefit by getting increased knowledge and skills in SDM, furthermore it may have future benefits, as the results of the study are likely to influence the implementation of SDM in Norway. There are no notable risks to participants in this study, and both groups receive the same training.

Where is the study run from?
University Hospital of North Norway

When is the study starting and how long is it expected to run for?
March 2016 to June 2019

Who is funding the study?
Northern Norway Regional Health Authority

Who is the main contact?
Simone Kienlin
simone.kienlin@helse-sorost.no

Contact information

Type(s)
Scientific

Contact name
Ms Simone Kienlin

ORCID ID
http://orcid.org/0000-0001-7367-2009

Contact details
Enggata 66
Hamar
Norway
2317
+47 (0)93642406
simone.kienlin@gmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15154

Study information

Scientific Title
Evaluation of a multidisciplinary training module in Shared Decision Making (Ready for SDM): a cluster randomized controlled trial

Acronym
Ready for SDM

Study objectives

The specialist health service in Norway includes the district Psychiatric Outpatient Services (DPS), where both patients with acute problems and those who need long-term follow-up can receive help. The intervention provided in this study addresses patient involvement in making medical decisions. The overarching aim of this approach is to enhance patient involvement by provision of evidence-based patient information, alongside with the patients' encouragement to participate in the decision process and thereby to increase the frequency of patient led informed choices. Patient involvement in this study is approached to via training of health professionals' communication skills. The psychiatric domain has been chosen as the medical context for the study, to demonstrate efficacy of the intervention.

Hypothesis: A 2-hour group training module can improve health professionals' communication competencies in Shared Decision Making (SDM), operationalized as accuracy of observer judgements regarding realized SDM made by use of the MAPPIN´SDM observer instrument.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The local ethics committee at the University Hospital in Northern Norway (UNN), ref: 2017 /1461
2. South-eastern regional ethics committee, ref: 2017/82 C

Study design
Cluster randomized waiting control group trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Shared decision making

Interventions
Participants are randomized to either an intervention or a waiting control group:

Intervention: an SDM training module addressing health professionals, which includes the following:
1. 30-min didactics, introduction to SDM
2. 30-min deepening in SDM

3. Interactive SDM observer training using a video-recording of a psychiatric consultation and a set of evaluation criteria
After administering a demographic questionnaire, the intervention group starts with the introduction module A, followed by B: SDM in-depth, and C: interactive training. After completion of modules A-C, primary and secondary endpoints are assessed.

Control: waiting/no intervention
Primary and secondary endpoints will be assessed as long as the group is untrained (has not yet received the training module). After the study, the training module will also be conducted for participants in the control group.

Intervention Type
Behavioural

Primary outcome measure
Accuracy of observation-based judgements made on SDM performance in a given medical consultation, which is provided as a video-recorded consultation. Judgements will be made in terms of the dyadic MAPPIN´SDM immediately after provision of the SDM training module or the waiting condition, respectively. Accuracy is calculated using weighted T coefficients calculated pairwise between participants' judgements and an expert standard rating.

Secondary outcome measures
SDM related knowledge assessed by using a five-item multiple choice knowledge test, previously used in a similar study. The level of achieved knowledge will be assessed immediately after provision of the SDM training module or the waiting condition, respectively.

Overall study start date
15/03/2016

Completion date
16/06/2019

Eligibility

Key inclusion criteria
1. Health professional teams from District Psychiatric Centers
2. Actively involved in psychiatric patient care

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
6-8 District Psychiatric Centers representing clusters in the study design, recruited from the South–Eastern Norway Regional Health Authority and the Western Norway Regional Health

Authority. Power calculation was made using G-Power program software. Based on data (mean values and SDs) from a previous comparable study, a given alpha of 0.05 and a power of 0.95 and allowing for use of two-tailed analysis, N=54 is needed per study group. Considering a cluster factor of 0.25 and an estimated drop-out rate of 25%, total sample size is N = 158 participants (control group: N=79; Intervention group: N=79), to not oversee a difference of 0.15 weighted T coefficient.

Total final enrolment
357

Key exclusion criteria
1. Non-health professionals and professionals from other settings than the pre-defined institutions
2. Health professionals working in administrative functions

Date of first enrolment
16/04/2018

Date of final enrolment
16/06/2018

Locations

Countries of recruitment
Norway

Study participating centre
Betanien District Psychiatric Center
Bergen
Norway
5145

Study participating centre
Bjørgvin District Psychiatric Center
Bergen
Norway
5113

Study participating centre
Øyane District Psychiatric Center
Straume
Norway
5353

Study participating centre
Kronstad District Psychiatric Center
Bergen
Norway
5054

Study participating centre
Solli District Psychiatric Center
Bergen
Norway
5228

Study participating centre
Voss District Psychiatric Center
Voss
Norway
5705

Study participating centre
Gjøvik District Psychiatric Center
Gjøvik
Norway
2819

Sponsor information

Organisation
University Hospital of North Norway

Sponsor details
Sykehusvegen 38
Tromsø
Norway
9019
+47 (0)77 62 60 00
post@unn.no

Sponsor type
Hospital/treatment centre

Website

https://unn.no/om-oss/university-hospital-of-north-norway

ROR
https://ror.org/030v5kp38

Funder(s)

Funder type
Government

Funder Name
Helse Nord RHF

Alternative Name(s)
Northern Norway Regional Health Authority

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Norway

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed, open access journal within one year after the overall trial end date. The results will also be presented at relevant national and international conferences.

Intention to publish date
16/06/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2020	04/06/2020	Yes	No

Results article	30/04/2021	04/10/2022	Yes	No
Results article	17/03/2022	10/06/2024	Yes	No