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Is it feasible to conduct a study to compare effectiveness of experience-focused counselling (EFC) and usual counselling for people hearing voices?

Submission date
18/12/2019

Recruitment status
No longer recruiting

Registration date
20/03/2020

Overall study status
Completed

Last Edited
02/01/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Hearing voices is a common symptom of psychosis and schizophrenia, but some people who do not have psychosis or schizophrenia hear voices. Current treatments attempt to reduce the voices or develop ways for people to cope with the voices. However, many people who hear voices find that medication and talking therapies do not provide much relief. Another approach is to think of the voices as part of the person and their life. The theory is that a person can develop a better relationship with the voices and accept them as part of their life. Experienced-Focused Counselling (EFC) aims to help a person to understand the connections between their individual responses to trauma and mental illness and how they experience the voices. Various different therapies can be used as part of EFC, including talking therapies, group therapy and music therapy. There has not been much research on whether EFC is effective.
The aim of this study is to investigate a larger-scale study can be conducted. It is also about getting some initial insights into the effects of EFC delivered by nurses for people hearing voices.

Who can participate?
Adults aged 18-65 years who hear voices and attend a community mental health centre in Bern (Switzerland) or Gürtersloh (Germany). They must be willing to discuss and interact with their voices.

What does the study involve?
Participants will be randomly allocated to one of two groups. One group will receive the usual counselling and treatment provided by the community mental health centre for 20 weeks. The other group will receive EFC, with 20 appointments over 20 weeks delivered by a trained nurse. The EFC programme involves a detailed interview to better understand the voices in the context of the life of the person, creating a report that describes the personal story of hearing voices from the person's perspective, an attempt to understand why the person is hearing the voices in the way they do, and development and practice of strategies enabling the person to negotiate with and take control of the voices.

During the study, all participants will fill in questionnaires at four timepoints: before the start of treatment, 10 weeks after the start of treatment, at the end of treatment (after 20 weeks) and 6 months after the end of treatment. The questionnaires will be completed with support of the study nurse. Questionnaires will measure topics like hearing voices characteristics and burden, the process of recovery, experience of psychosis, controlability of the voices and severity of symptoms related to the mental illness.

What are the possible benefits and risks of participating?
Participating in the study might have no direct benefit for study participants; however, participants in both groups might experience benefit from the treatment they receive. EFC was developed based on the experience and recommendations of people who hear voices. Experience from using EFC and from previous research suggests that few risks are expected. Especially at the beginning, a participant might experience their voices as louder or more distressing. An EFC Counsellor will support the participant in dealing with this situation.

Where is the study run from?
University Hospital for Psychiatry and Psychotherapy in Bern (Switzerland)

When is the study starting and how long is it expected to run for?
November 2019 to March 2023

Who is funding the study?
Foundation of the Bern University Services for Psychiatry (Switzerland)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2019-01093 Version 1.2 05/11/2019

Study information

Scientific Title
Pilot study of a randomized, controlled, single-blinded interventional study on the effectiveness of experience-focused counselling (EFC) for people hearing voices

Acronym
EFC-Pilotstudy

Study objectives
The primary goal of this pilot study, as a small version of a planned main study, is to clarify whether the most important components of the study, such as recruitment, randomization, intervention and assessments, work well together and whether they are suitable for implementation in a main study.
In order to obtain initial insights into the effectiveness of the intervention, the following hypotheses relevant to a main study are defined. The guiding principle here is to use the intervention to reduce the burden related to hearing voices and to improve the ability to control the voices.
Hypothesis: Experience-focused counselling (EFC) is better than treatment-as-usual (TAU) counselling with similar time spent on it.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/12/2019, Kantonale Ethikkommission fuer die Forschung Bern [Research Ethics Committee of the Canton of Bern] (Murtenstrasse 31, 3010 Bern, Switzerland; +41 31 633 7070; info.kek.kapa@gef.be.ch), ref: 2019-01093

Study design
Multicenter randomized controlled single-blinded interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)

Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet, which is only available in German.

Health condition(s) or problem(s) studied
Hearing voices in the context of mental health problems

Interventions
Randomisation:
In order to have a similar distribution of the study participants on both study-sides, randomization is carried out separately for both study sides as block randomization. This takes place after submission of the informed consent and the first assessment-interview (t0) and is carried out by an independent person non-involved otherwise in the study.
Procedure:
1. Creation of a random number list for each site according to the block length of 24 (participants) using a random generator.
2. Attribution to each block by means of a corresponding number of cards with the indication to which group (intervention or control) the participant is assigned. Each card will be sealed in opaque envelopes. When all envelopes are closed, they will be mixed and then be assigned with the numbers (1a-24a and 1b-24b) per block.
3. Upon each allocation from the study nurse of a new study participant, the independent person consults the random number list of the attributed block and takes the envelope according to random number out and sends the information to the corresponding group the participant was allocated to.

Experience-Focused Counseling (EFC) delivered by nurses:
In this arm, EFC will be given to voice hearers by qualified trained nurses. EFC consists of three major parts: the Maastricht Interview, Report and Construct, alongside the development of coping strategies. EFC is offered over 20 weeks in 20 appointments. All three parts of the intervention (Maastricht Interview, Report and Construct) should evenly take place during the course of the 20 appointments.

Treatment as Usual (TAU):
In this group, voice hearers will receive nurse-delivered unspecific counselling as usual. TAU is offered over 20 weeks without a specification regarding the number of appointments.

Intervention Type
Behavioural

Primary outcome measure
Characteristics of the voices and related burden assessed using the Psychotic Symptom Rating Scales (PSYRATS) at baseline (upon inclusion but before being assigned to the group; T0), after 10 appointments (T1), upon completion of the intervention (T2) and 6 months after completion of the intervention (follow-up; T3)

Secondary outcome measures
1. Locus of control assessed using the Multidimensional Health Locus of Control Scale (MHLC, Form-C) at baseline (upon inclusion but before being assigned to the group; T0), after 10 appointments (T1), upon completion of the intervention (T2) and 6 months after completion of

the intervention (follow-up; T3)
2. Personal Recovery assessed using the Questionnaire about the Process of Recovery (QPR) at baseline, T2 and T3
3. Subjective experience and meaning of psychosis or hearing voices assessed using the Subjective Sense in Psychosis Questionnaire (SUSE) at baseline, T2 and T3
4. Use of antipsychotic medication assessed using the patient's medical records, with the medication used converted into chlorpromazine equivalents, at baseline, T2 and T3
5. Psychopathology severity assessed using the Brief Psychiatric Rating Scale Expanded (BPRS-E) at baseline, T2 and T3
6. Qualitative assessment of the participant's views on the study burden and feasibility of a larger study assessed by interview at T2
7. Sociodemographic and health-related data assessed using an investigator-designed questionnaire at baseline, T1, T2 and T3

Overall study start date
01/11/2019

Completion date
31/03/2023

Eligibility

Key inclusion criteria
1 Aged over 18 and under 65 years. This data is gathered from the patient record.
2. Presence of hearing voices or acoustic hallucination as a perception without external stimulus source. This criterion will be collected from the patient record and will be validated at the first contact before informed consent.
3. Experiencing distress from the voices. This will be validated with the Psychotic Symptom Rating Scales (PSYRATS) with at least one non-zero score on questions 8, 9, or 10.
4. Willingness to participate regularly in conversations about voice hearing: This will be validated at the first contact before informed consent.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
40

Total final enrolment
21

Key exclusion criteria
1. Inability to consent: This is regularly noted in the patient record by the doctor in charge. The nurses at the community mental health centers will be asked this question.
2. Not able to speak and understand (Swiss) German: This will be assessed by the study nurse based on the conversation at first contact.
3. Acuity: If the person is in an acute crisis situation and is unable to follow 15 minutes long conversation. This information can be obtained from the responsible nurse or doctor on the unit or can be assessed by the study nurse based on the first contact conversation.

Date of first enrolment
15/09/2020

Date of final enrolment
31/03/2022

Locations

Countries of recruitment
Germany

Switzerland

Study participating centre
University Hospital of Psychiatry and Psychotherapy
Bolligenstrasse 111
Bern 60
Switzerland
3000

Study participating centre
LWL Hospital of Psychiatry of Gütersloh
Buxelstrasse 50
Gütersloh
Germany
33334

Sponsor information

Organisation
University Hospital for Psychiatry and Psychotherapy

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Sponsor type
Hospital/treatment centre

Website
https://www.upd.unibe.ch/research/university_hospitals/university_hospital_of_psychiatry_and_psychotherapy/index_eng.html

Funder(s)

Funder type
University/education

Funder Name
Foundation of the Bern University Services for Psychiatry

Results and Publications

Publication and dissemination plan
This study will be conducted in support of a doctoral thesis.
1. There is the plan to publish an article related to answering the primary research question, which whether the most important components of the study, such as recruitment, randomization, intervention and assessments are working well together and whether they are suitable for implementation in a main study.
2. A second article is planed to describe initial insights into the effectiveness of the intervention, related to reduce the burden related to hearing voices and to improve the controllability of the voices.

Intention to publish date
01/10/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available because data were collected in accordance with the Swiss Human Research Act, which prohibits the disclosure of the data. On request, it can be clarified to what extent data can be made available.

IPD sharing plan summary

Available on request, Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	protocol version 1.3	18/08/2020	23/03/2023	No	No
Results article	in German	16/10/2023	02/01/2024	Yes	No
Thesis results	in German	01/09/2022	02/01/2024	No	No