

Effectiveness of psychotherapy in patients with medically unexplained physical symptoms

Submission date 09/05/2018	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 14/05/2018	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 05/07/2022	Condition category Signs and Symptoms	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Mental health professionals, as well as doctors, often see patients presenting physical symptoms for which a physical cause is either absent or does not explain these complaints sufficiently. While in general language these conditions are often called “psychosomatic” (caused by a mental factor) the term “medically unexplained physical symptoms” (MUPS) has been coined in the medical context. Given the importance of psychological factors in the cause of MUPS, psychological treatments represent a promising approach to the treatment of patients with MUPS. However, reviews and meta-analyses have shown that while various forms of psychological treatments are effective in the treatment of MUPS, the ability to get results is rather low. While some studies indicated that higher effects may be achieved by longer treatments and by more complex approaches, the volume of research is small. Therefore, the full potential of psychological treatments for MUPS remains unexplored.

This study aims to assess the effectiveness of a multi-component psychological treatment in the treatment of patients with MUPS and to examine the process of the therapeutic change.

Who can participate?

Adult patients aged over 18 years who enter group-based psychological treatment in the participating clinics.

What does the study involve?

Participants receive a psychological treatment made up of group psychotherapy, supplemented by activities such as relaxation training, yoga, and art therapy. It is provided on daily basis (5 days /week) for a period of 6 to 12 weeks.

What are the possible benefits and risks of participating?

We do not anticipate any side effects of the participation in our study.

Where is the study run from?

1. Psychosomatic Clinic, Prague (Czech Republic)
2. Psychotherapeutic and Psychosomatic Clinic ESET, Prague (Czech Republic)
3. Day Care Center „Karlovy“, Psychiatric Clinic of the General University Hospital in Prague (Czech Republic)

4. Day Care Center Horní Palata, General University Hospital in Prague (Czech Republic)
5. Psychiatric Hospital, Šternberk (Czech Republic)

When is the study starting and how long is it expected to run for?
January 2018 to December 2020

Who is funding the study?
The Czech Science Foundation (Czech Republic)
Grantová Agentura České Republiky

Who is the main contact?
Dr Tomáš Řiháček (Scientific)
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
GA18-08512S

Study information

Scientific Title
Effectiveness of psychotherapy in patients with medically unexplained physical symptoms: A multi-site naturalistic study

Study objectives
EFFECTIVENESS HYPOTHESES
H1: Patients with medically unexplained physical symptoms (MUPS) report decrease in the

intensity of MUPS after psychotherapy (primary outcome).

H2: Patients with MUPS report decrease in depression after psychotherapy.

H3: Patients with MUPS report decrease in anxiety after psychotherapy.

H4: Patients with MUPS report decrease in general distress after psychotherapy.

H5: Patients with MUPS report increase in well-being after psychotherapy.

H6: Patients with MUPS report increase in role functioning after psychotherapy.

CHANGE MECHANISM HYPOTHESES

H7: Decrease in MUPS intensity is preceded by increase in somatic awareness.

H8: Decrease in MUPS intensity is preceded by increase in emotional regulation skills.

H9: Decrease in MUPS intensity is preceded by increase in acceptance of symptoms.

H10: Decrease in MUPS intensity is preceded by increase in satisfaction of a patient's relational needs.

H11: Decrease in MUPS intensity is preceded by increase in the clarification of meaning.

H12: Decrease in MUPS intensity is predicted by the quality of therapeutic alliance.

H13: Decrease in MUPS intensity is predicted by the quality of group cohesion.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Research Ethics Committee of Masaryk University, 30/01/2018, ref: EKV-2017-029-R1

2. Ethics Committee of the General University Hospital Prague, 15/02/2018, ref: 2143/17 S-IV

Primary study design

Interventional

Study design

Multicentre pre-post study of psychotherapy effectiveness

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Medically unexplained physical symptoms (MUPS)

Interventions

Multi-component psychological treatment is provided to all participants on a daily basis. The core of the treatment is group psychotherapy provided with a frequency of 2 to 5 times a week for a period of 6 to 12 weeks, supplemented by activities such as relaxation training, yoga, and art therapy. This is a naturalistic study and the intervention is not at the discretion of the investigator. While the composition of the treatment package differs slightly across participating clinics, the defining aspect (i.e., group psychotherapy) is present in all settings.

Intervention Type

Behavioural

Primary outcome(s)

Intensity of medically unexplained physical symptoms is measured using PHQ-15 at the beginning of the treatment, weekly during the treatment, at termination, and 6 and 12 months after termination.

Key secondary outcome(s)**SECONDARY OUTCOMES**

1. General distress is measured using ORS at the beginning of treatment, weekly during treatment, and at termination.
2. Depression is measured using PHQ-9 at the beginning of treatment, at termination, and 6 and 12 months after termination.
3. Anxiety is measured using GAD-7 at the beginning of treatment, at termination, and 6 and 12 months after termination.
4. Well-being is measured using WHO-5 at the beginning of treatment, at termination, and 6 and 12 months after termination.
5. Role functioning is measured using selected items from PHQ at the beginning of treatment, at termination, and 6 and 12 months after termination.

HYPOTHESIZED MEDIATORS OF CHANGE WHICH, THEMSELVES, REPRESENT SECONDARY OUTCOMES

6. Somatic awareness is measured using MAIA at the beginning of treatment, weekly during treatment, and at termination.
7. Emotion regulation skills are measured using ERSQ at the beginning of treatment, weekly during treatment, and at termination.
8. Acceptance of symptoms is measured using CPAQ modified at the beginning of treatment, weekly during treatment, and at termination.
9. Satisfaction of relational needs is measured using RNS-20 at the beginning of treatment, weekly during treatment, and at termination.

Completion date

31/12/2020

Eligibility**Key inclusion criteria**

1. Age of 18 or more years
2. Occurrence of at least one somatic symptom with a duration of at least six months not fully explained by any somatic diagnosis

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

Key exclusion criteria

1. Diagnosis of a severe mental disorder that would make participation in this kind of treatment impossible
2. Diagnosis of an organic disease responsible for the symptoms

Note: All patients willing to participate are included in the study. Primary analysis is conducted on patients with MUPS. Secondary analyses, however, are conducted on the whole sample (i.e., including patients without somatic symptoms and those with somatic symptoms explained by an organic disease).

Date of first enrolment

26/01/2018

Date of final enrolment

31/12/2019

Locations**Countries of recruitment**

Czech Republic

Study participating centre

Psychosomatická klinika

Patočkova 3

Prague

Czech Republic

169 00

Study participating centre

Denní sanatorium Horní Palata Všeobecné fakultní nemocnice v Praze a 1. lékařské fakulty

Univerzity Karlovy

U Nesypky 28

Prague

Czech Republic

150 00

Study participating centre

Denní stacionář Karlov Všeobecné fakultní nemocnice v Praze a 1. lékařské fakulty Univerzity

Karlovy

Ke Karlovu 11

Prague

Czech Republic

121 08

Study participating centre**Psychoterapeutická a psychosomatická klinika ESET**

Úvalská 47

Prague

Czech Republic

100 00

Study participating centre**Psychiatrická nemocnice Havlíčkův Brod**

Rozkošská 2322

Havlíčkův

Brod

Czech Republic

580 01

Study participating centre**Psychiatrická klinika Fakultní nemocnice Hradec Králové**

Sokolská 581

Hradec

Králové

Czech Republic

500 05

Study participating centre**Fakultní nemocnice Ostrava, Oddělení psychiatrické**

17. listopadu 5

Ostrava-Poruba

Czech Republic

708 52

Sponsor information**Organisation**

Faculty of Social Studies, Masaryk University

ROR<https://ror.org/02j46qs45>

Funder(s)

Funder type

Research organisation

Funder Name

Grantová Agentura České Republiky

Alternative Name(s)

Grant Agency of the Czech Republic, Czech Science Foundation, Grantová agentura ČR, Grantové agentury, GrantovaAgentura, GAČR, GACR, GA ČR, GA CR

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Czech Republic

Results and Publications

Individual participant data (IPD) sharing plan

Current IPD sharing statement as of 26/03/2019:

The individual participant questionnaire data collected during the trial will be shared, after deidentification. The data will be made available upon reasonable request for three years after the end of the project. Afterwards, it will be made available to anyone who wishes to access it with no end date. The Data Set, Statistical Analysis Plan and Analytic Code will be made available at <https://osf.io/dfrma/>

Previous IPD sharing statement:

The datasets generated during and/or analysed during the current study are/will be available upon request from Tomáš Řiháček, rihacek@fss.muni.cz

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2022	04/07/2022	Yes	No