CONSORT Research Protocol

Mentalization-based Mental Health Educartion in a naturalistic patient population from a psychiatric out-patient clinic in North Norway: A randomized controlled study.

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The headings in this protocol refer to the CONSORT template.

Content

Pre-Trial Part

Title

Mentalization-based Mental Health Education
in a naturalistic patient population
from a psychiatric out-patient clinic in North Norway:
A randomized controlled study.

1b Abstract

To be written in the scientific article following the trial.

Introduction

2a Background

Mentalizing (Mz) is a psychodynamic concept which captures our ability to recognize and think about ones own and other peoples thoughts and feelings. Mentalizing is related to a wide range of other scientifically and historically rooted concepts such as: Metacognition, reflective function, executive function, theory of mind, externalization, self-control, self-consciousness and thoughtfulness. Mentalizing has fundamental significance for mental & social functioning (Fonagy 2002, Liotti 2011).

Intensive Mentalization-Based Therapy/Training (MBT) for Borderline Personality Disorder (BPD) has shown very promising long-term results (Batemann 2008). That has stimulated a wider interest into this treatment approach.

This fundamental approach - to teach and practice thinking - especially how to think carefully in critical situations, we consider to be in line with the field of ***P***-factor theory and research (Caspi 2018) which indicates that severe ***P***sychopathology in general is rooted in fundamental neurobiological vulnerability of thinking - often caused by genetics and trauma - that is compromized mentalizing.

P-factor and Mz theory and research set a perspective for a wider application - that is efficient mental health promotion and prevention of mental health disease on a public health level - which also has been called for for health economic reasons (Kadzin 2011, Roth 2006).

We responded to this call 15 years ago by developing an Mz-based Mental Health Education Program which has since been tested in various public health domains & countries.

Our Mz program focus on how we as humans can use *the strongest tools in the world - our Thoughts* - to protect ourself and each other and boost mental repair - especially when life is hard. It is not *Psychoeducation* about the characteristics of specific disorders/symptoms - it is Mental Health Education in daily language - how to reinforce our basic common life toll - *thoughts* - in order to cope with life challenges (references on www.thoughtful.house/science).

The program is designed to optimize personal (user-driven) meaningfulness and has been tested during 15 years in several countries. Results fra Denmark, Greenland and Italy indicate that the program can help to reduce conflicts, stress and sick leave and support mentalizing & learning in different populations (Bak 2015, Lundgaard Bak 2018, Lundgaard 2021, Valle 2016).

Based on these experiences and results, we have in 2020-2021 developed a new, expanded and more user friendly version - called *Thoughtful* - as a web-based self-treatment program which can be found on www.tenksom.house (Norwegian), www.thoughtful.house (English) and www.omtanke.house (Danish). Greenlandic and Italian versions are expected to be published in 2023.

The Thoughtful/Mz program approach is developed in line with decades of evidence on a meta-analytical level about the efficiency of patient education for somatic and mental disorders - that is *a general recovery approach*.

For transparency the program has a science theme in which comprehensive theory and research behind and about the program on www.thoughtful.house/science - including our E-book *Thoughts behind Thoughtful - Theory & Research*.

In Appendix 2 in this protocol you will find a short introduction to the Thoughtful program.

The Thoughtful program is a supplemental effort to any other measures aiming to support peoples life skills - in any life domain. It is a self-directed program which means that it can be introduced with a minimum of ressources within any organization.

2b Objectives

The objective of the current naturalistic/pragmatic randomized study is to test the feasibility and efficiency of the Thoughtful program in an unselected waiting list patient population from a psychiatric out-patient clinic in the University Hospital of North Norway.

Methods

3a Trial Design

This is a randomized clinical trial in which individual waiting list patients are allocated 1:1 into intervention group and control group.

3b Changes to methods after trial commencement

NONE.

4a Participants

All norwegian speaking patients on the outpatient clinic waiting list are considered eligible for the study. Thus no patients will be a priori excluded from the study population for any clinical reason - for instance diagnosis, co-morbidity, symptom severity or use of medicine or other kinds of treatment.

So this is an intention-to-treat & naturalistic/pragmatic trial design.

No patients will be excluded from *treatment as usual* because of the trial.

4b Settings

The outpatient clinic is a part of a general District Psychiatric Centre in North Norway (Harstad). The clinic is serving a population of 31.300 citizens (mixed rural & small city population in 4 municipalities: Harstad, Lødingen, Sjelsund & Kvarfjord). The centre also has an inpatient ward and an emergency team.

The centre treats all categories of psychiatric disorders with a broad range of psychoterapeutic, medical and somatic assessments and measures.

Because this is a naturalistic/pragmatic study the patient population will be a mix with respect to socio-demographic and psychopathological parameters - and with respect to length of waiting period & previous treatment measures.

According to The World Bank & OECD Norway is one of the richest countries in the world with low social inequality.

Relevant data for the study are collected from the electronic patient record system and a separate research survey database.

5 Intervention

Based on the theories and research mentioned above *patients in the intervention group* will be invited to join a group-based 6 hour *Thoughtful* course (8 patients per group). *Two delivery models will be tested:*

- A: 2 hour session per day - 3 days in a row in one week.
- B: 1 day 6 hour course.

Audios from the web-program and an illustrated book with core concepts & themes are demonstrated. Everything lectured can be reviewed at home by participants in greater details in the Audios and the book.

In group A patients are offerede an indivdual session 1 month after the course.
Group B patients are offered individual session when needed.

The course has been approved by the University Hospital as a documented treatment equated with other standard treatments.

The Thoughtful course is an *educational* course where participants are offered research-based knowledge in daily language about thinking. So patients can participate without telling anything about their personal challenges - just be present - anonymous - listen - and think. Naturally they are welcome to tell and ask - but it is not a requirement. In the hour immidiately after each session participants are offered a short individual talk if needed. Pilot experiences show that participants are comfortable with this approach.

All patients enrolled in the trial - in the intervention group and in the control group - will keep their position on the wating list and will have access to individual assessment and treatment as usual. So the *Thoughtful* intervention is a *supplemental* effort which does not affect standard procedures or patient legal rights.

Pasients who are not able to join the group course because of social anxiety or practical reasons will be given course materials for self study and they will be offered individual introduction.

This delivery model has several advantages:

- In *the Thoughtful program* knowledge is presented in an illustrated book and in sound files (Audios) which makes it possible for people who dont read to join anyway. People who dont want to talk about their thoughts and feelings - who are not comfortable about sharing their burdens with others - can also join - that is self-treatment.
- Patients with for instance social anxiety and/or low mental energy level who have difficulties joining standard talking-therapy will in this way have access in a home setting to research-based self-treatment knowledge and training-tools. They can repeat the lectures any number of times and at times which suits them best. They can study alone or in companion with relatives or friends who support them.

- High fidelity is inherent in this kind of program as the material presented in book and audio files remains the same no matter how many times it is used and it is independent of variations in therapist approaches. The content of the intervention can be shared widely exactly as tested in randomized control trials.

- *Thoughtful* is a modular user-driven program. Research indicates that modular user-driven programs may have double clinical efficacy compared with standard delivery models (Weisz 2012).

- Research indicates that self-help materials supplemented by professional guidance may reduce symptoms in comparison to waiting list or control treatment and may produce comparable outcomes to formal therapist-delivered psychological therapies. Self-help concepts may thus have utility as a first step in treatment (Perkins 2009).

  In the current trial the web-based program is combined with options for direct professional contact. Thus the individual patient can tailor the intervention to his/her own needs and circumstances.

6a Outcomes

Primary outcome will be *use of mental health hospital services* measured by the number of contact/ treatment days to the centre (in-patient, out-patient and emergency team contacts) in a 12 month follow up period from the day of intervention start. This outcome measure is considered to have a high face validity and to be a reliable proxy measure for patient wellbeing when applied within a consistent organizational context (Burns 2007, Addington 2012).

Seconday outcomes will be:

- Average change in score *before* and *6 months after* intervention on a 3 item anonymous mental wellbeing questionnaire - se Appendix 1.

- Medication level based on pharmacy data.

The use of standard patient record data as outcome measures is in line with the Recommendation on Criteria for Establishing Strong Evidence of Effectiveness from a National Academies Report (O'Connell 2009).

A trial group sample of participants will be interviewed for a qualitative research study.

6b Any changes to trial outcomes after the trial commenced

NONE

7a Sample size

The total number of contact/treatment days in the centre (out-patient clinic, inpatient ward and emergency team) in 2021 was 14.621 = 1250 contact days per 100 patients.

Based on a standard deviation of 100 days, Type 1 error level of 5%, a 5% expected reduction of total number of contact days per year in the intervention group, we will need 64 patients in the intervention group and 64 patients in the control group in order to obtain a statistical power of 0,80.

Currently around 300 patients are on waiting list. Prioritizing long waiting time we enroll and randomize 256 patients in the trial:

- 64 patients in trial group A (3-day course) & 64 pasients in control group A.
- 64 patients in trial group B (1-day course) & 64 patients in control group B.

So we expect this to be a reliable study with acceptable statistical power.

7b Interim analyses and stopping guidelines - when applicable

NONE

Randomization

8a Sequence generation,
9 Allocation concealment mechanism
10 Implementation

During the trial period 64 waiting list patients per month in 4 months will be allocated.
The patients are 1:1 computer randomized to trial/control group.

See also 11a.

8b Type of randomisation; details of any restriction (such as blocking and block size):

NO RESTRICTIONS.

11a Blinding

It is not possible in this kind of intra-clinic research to completely blind either patients or therapists. For legal reasons individual treatment plan & course must be described in the electronic patient record. There is also an unavoidable risk that individual patients in the trial groups - or therapists - will talk about eventual Thoughtful program experiences - which may potentially "contaminate" control group patients with Thoughtful knowledge. The size of this risk is probably proportional to percieved benefit. A consequence may be a lowering of effect size.

Moreover the program is freely accessible on the internet - although the Norwegian version is only published shortly before trial start. The reason for this open access approach is that a log-in procedure is considered to be a major obstacle for vulnerable psychiatric patients. From an ethical perspective we also consider that open access to *vital knowledge about life-threatening thoughts* is crucial - for patients and for their primary supportive social network.

12a Statistical methods

ANOVA wil be used for the statistical analysis.

12. Subgroup analyses

Based on the sample size & power calculation we expect that it will be possible to analyse on the level of the two delivery groups A & B. It may be also be feasible to analyze the use of the 3 service subgroups in the center: Outpatient clinic, emergency team and inpatient ward.

Post-Trial Part

Results & Discussion

To be written in the scientific article following the trial.

Other Information

Project organization

This project is conducted by the Harstad District Center for Psychiatry in the University Hospital North Norway in cooperation with the University Hospital Research Department. Project managers are:

- Audun Eskeland (DSPHA-UNN). Center Manager
- Poul & Louise Lundgaard, MD & Pd.B.
  Thoughtful Program founders, researchers & intervention therapists:

  Poul is a medical doctor. Previously: Head of Health in Ringkoebing County, Denmark. Head of Health Aarhus Municipality, Denmark. Chief Physician Danish Committee for Health Education. Public Health researcher Aarhus University, Denmark. Clinical experience in Neurology, Psychiatry & Psychotherapy (Children, Adolescents, Adults). Consultant for the Greenlandic Government on Suicide prevention. Mz Program developer & researcher.

  Louise is a social educator. Previously: Years of mentalizing work experience with vulnerable children & young people and families in residential institutions in Denmark & Greenland. Including Department Head at the Orphanage in Tasiilaq in Greenland. Consultant for refugee families in Helsingor Denmark. Consultant for the Greenlandic Government on Suicide prevention. Mz Program developer & researcher.

  P & L expertise is Mentalization / Metacognition and Mind-Body Medicine.

  We are employed in the District Psychatric Center Harstad at the University Hospital North Norway - working with patient assessment & treatment, research and program development.
- The University Hospital Research Department provides methodological and technical support.

Ethics

This is not a biomedical intervention but a mental health education health service research project. For that reason the Norwegian Research Ethical Committee has decided that this project doesn't need approval from the committee.

In 2013 The National Ethics Committee in Denmark likewise jugded that randomized studies of the Thoughtful program in Denmark were not within their jurisdiction.

The Thoughtful program consists of research-based knowledge in daily language about mentalizing. For transparency all relevant research papers and books are freely available on the program website.

There is an increasing awareness that mental health work can have side effects - just as medication can have side effects. Research indicates that a disturbingly large number of people (20-30%) get worse when they attend psychotherapy - even though all guidelines for the therapy have been complied with (Flor 2019, Lundgaard 2021). Side-effects are caused by internal re-traumatizing if you *only* talk about "dark thoughts". In the Thoughtful theme *Basic* this mechanism is discussed in detail. Mentalizing strategies seem to be one way to reduce this risk of talking-therapy (Batemann 2008).

In this context it is relevant to ask: "Can Thoughtful have side effects?" To answer this question we will make an analogy: When we learn to *read and write*, it opens a new & wider world of sharing knowledge and experiences. If you incidentally read a book that makes you feel bad you won't blame the skill of reading - but you may eventually blame the book - or your choice to read the book. Likewise if you write a letter to a person who becomes upset - you may regret the way you wrote the letter but you won't regret that you learned how to write.

Thoughtful is basic knowledge about *how to read your own thoughts and write new thoughts.* So that you can reinforce your innate thinking-skills and qualify *what* to think about - that is to be thoughtful. This is in all respects comparable to the skill of reading and writing - which naturally per se is just a physical expression of thoughts.

If you end up in a troublesome situation which is difficult to solve - it is not the basic Thoughtful knowledge about how to "read your own thoughts and write new thoughts" that is the problem - it is the circumstances in the situation that will cause your discomfort and suffering. An improved level of thinking - mentalizing - is most often helpful when emotions & feelings are troublesome - then you can think more thoroughly about your emotional state and take appropriate actions. That is why this approach actually may *reduce* the risk of side effects in psychotherapy and mindfulness/meditation practices and make it safer. Because one is better equipped to take responsibility for what happens.

Data protection

Anonymous administrative data are extracted for statistical analysis from the authorized University Hospital Patient Record system DIPS ARENA.

Anonymous questionnaire data are recorded and stored in the approved University Hospital Research data center.

Data storage and analysis will apply to EU GDPR standards.

Timeline

Patient enrollement is expected to start in march 2023 and continue for 4 months.

Follow up period is 1 year.

So data analysis is expected to start in july 2024.

Clinical trial registration

This trial will be registered on clinicaltrial.gov

Conflict of interests

NONE

Budget & Funding

All costs are covered by the University Hospital North Norway. So there will be no external funding.

References

Addington DE, McKenzie E, Wang J. Validity of Hospital Admission as an outcome Measure of Services for First-Episode Psychosis. Psychiatric Services 2012(63(3):280-2.

Bak PL, Midgley N, Zhu JL, Wistoft K and Obel C (2015) The Resilience Program: preliminary evaluation of a mentalization-based education program. Front. Psychol. 6:753. doi: 10.3389/fpsyg.2015.00753.

Bateman A, Fonagy P (2008). 8-Year Follow-Up of Patients Treated for Borderline Personality Disorder: Mentalization-Based Treatment Versus Treatment as Usual . Am J Psychiatry;165:631–638.

Burns T. Hospitalization as an outcome measure in schizophrenia. Br J Psych 2007;191(59):37-41.

Caspi A, Moffitt TE. All for One and One for All: Mental Disorders in One Dimension. Am J Psychiatry 2018;175(9):831-44.

Fonagy P, Gergely G, Jurist E, Target M (2002). Affect Regulation, Mentalization and the Development of the Self. Other Press.

Flor JA, Kennair LEO. Harmful Help: The possible negative effects of psychotherapy. Skadelige samtaler. Myten om bivirkningsfri terapi. Tiden Norsk Forlag 2019.

Hazell et al. Serial measurement of mood via text messaging in young people. Child Adolesc Psychiatry Ment Health 2020;14(5)1-6.

Kazdin AE, Blase SL. Rebooting Psychotherapy Research and Practice to reduce the Burden of Mental Illness. Perspectives on Psychological Science 2011;6(1):21-37.

Liotti G, Gilbert P (2011). Mentalizing, motivation and social mentalities. Theoretical considérations and implications for psychotherapy. Psychology and Psychotherapy Research and Practice 2011;84:9-25.

Lundgaard Bak, P. (2018). Resilience; A practical guide to teamwork with children and adolescents. Routledge.

Lundgaard P & L (2021): *Thoughts behind Thoughtful - Theory & Research*. And *Thinkinuk in Greenland*. www.thoughtful.house/science.

Løberg M, Kalager M, Bretthauer M. Randomize, Then Consent or Consent then Randomize. Epidemiology 2016;27(3):3934.

O'Connell ME, Boat T, Warner KE. Preventing Mental, Emotional, and Behavioral Disorders among Young People: Progress and Possibilities. National Research Council and Institute of Medicine 2009.

Perkins SSJ, Murphy RRM, Schmidt UUS, Williams C. Self-help and guided self-help for eating disorders (Review). The Cochrane Library 2009, Issue 1.

Relton C, Torgerson D, O'Cathain A, Nocholl J. Rethinking pragmatic randomised controlled trials: Introducing the cohort multiple randomised controlled trial design. BMJ 2010;340:c1066.

Richmond et al. Feasibility, acceptability and validity of SMS text messaging for measuring change in depression during a randomised controlled trial. BMC Psychiatry 2015;15(68):2-13

Roth A, Fonagy P: What works for whom (2 Ed.). Guildford Press 2006.

Valle A, Massaro D, Castelli I, Sangiuliano Intra F, Lombardi E, Bracaglia E and Marchetti A (2016) Promoting Mentalizing in Pupils by Acting on Teachers: Preliminary Italian Evidence of the "Thought in Mind" Project. Front. Psychol. 7:1213. doi: 10.3389/fpsyg.2016.01213.

Weisz JR, Chorpita BF, Palinkas LA, Schoenwald SK, Miranda J, Bearman SK, Daleiden EL, Ugueto AM, Ho A, Martin J, Gray J, Alleyne A, Langer DA, Southam-Gerow MA, Gibbons RD: Testing Standard and Modular Designs for Psychotherapy Treating Depression, Anxiety, and Conduct Problems in Youth. A Randomized Effectiveness Trial. Arch Gen Psychiatry 2012; 69(3):274-82.

Appendix 1: Questionnaire

Both Intervention and control group participants will be asked to answer 3 questions *anonymously* before intervention and 6 months later - via the University Research Department survey program Redcap.

How are you? Answer with a number between 0 and 9: 0 = Very bad - - - - 9 = Very good
Can you use your thoughts to take care of yourself? Answer with a number between 0 and 9: 0 = Never/Dont know - - - - 9 = Always
Do you have suicidal thoughts? Answer with a number between 0 and 9: 0 = No suicidal thoughts - - - - 9 = Serious suicidal thoughts

Appendix 2: Short Program info

Thoughtful www.thoughtful.house

It is vital that the body and the mind can repair itself.
Therefore Nature has taken advantage of
every opportunity to refine its own repair workshop.

Thoughts are the most powerful tools in the world.
So it is natural - and documented by science -
that thoughts can boost repair and healing
in the mind and the body.

It works because the brain and the body translate
our thoughts into its own chemical language
in our cells and our genes.

Thoughtful is a mentalization-based Mental Health Education program with knowledge and stories in everyday language about the world's most powerful tool - our Thoughts. How we can use our thoughts to protect ourselves and each other - and reinforce repair in the mind & body.

Thoughtful is currently available in Norwegian (www.tenksom.house), English: www.thoughtful.house & Danish: www.omtanke.house. A Greenlandic version and an Italian version will be published in 2023.

Thoughtful has a particular focus on brief Audios - because Audio is flexible: You can listen discretely and without any effort - when you are tired or exhausted - and when you are full of energy & multi-task. The program also includes an illustrated book with basic concepts and appetizers.

The Thoughtful Audios are designed for acute use - just like a pain killer - and for regular use - just like vitamin pills. Thoughtful is *Thought-Medicine* with huge advantages: It have no side effects and the positive effects increase with regular use. In critical situations Thoughtful Audios can be used in frequently repeated doses - just like intensive care medicine.

Thoughtful is for everyone - in health and disease - privately, in the family, in kindergarten, school, education, at work and in treatment. Because Thoughtful is Audio-based everyone can participate, including people who do not read, and people who do not want to or are able to share their thoughts and feelings with others.

Thoughtful is based on neurocognitive research - especially mentalization. Research has documented that mentalization-based psychoeducation & practice can have long term positive effects even for people with severe psychatric disease (Batemann & Fonagy - see www.thoughtful.house/science).

Research in Denmark has indicated that the Thoughtful program can contribute to a reduction of serious conflicts by 90% and a halving of staff sickness absence in socially disadvantaged residential areas - stable over 3 years. Research in Italy has indicated that Thoughtful can help improve mentalizing in children to an extent never before measured in the world (See www.thoughtful.house/science).

In Greenland we have published a book with the program's basic knowledge & stories, which citizens and professionals can request for free. In 2018-19, 10,000 books were handed out - in a population of 56,000 people. This indicates a high program feasibility.

Background research, our own research, our articles and books with practical experiences can be found at www.thoughtful.house/science. Including the book *Thoughts behind Thoughtful - Theory & Research* - with about 200 scientific references - background research & our own research. And a book about *Thinkinuk in Greenland*, and a Danish prison project report with prison-staff and drug-addicted mentally ill detainees.

The program is freely available because it is our position that all people should have free access to *vital knowledge about serious and life-threatening thoughts.*

Thoughtful integrates with any other effort.

Finally, here are two real-life stories about people who have used Thoughtful:

1.
A person with life sentence for murder. He suffers from severe mental illness and drug addiction. After 3 weeks of using the Thoughtful Audio *The Pharmacy of the Brain*, he reported that he no longer had any drug-craving. He told that this was a better fix than heroin and it worked better for him than mindfulness. Several years later, he still uses *The Pharmacy of the Brain* on a daily basis.

2.
13 year old teenager with suicide attempt - childhood trauma due to severe neglect. The day after the suicide attempt, she was offered *life-saving knowledge about life-threatening thoughts* while still at the hospital - so that she immidiately could protect herself in a very stressful life situation.

A few days later, a Thoughtful session was arranged with the patient, her parents and a friend who had attempted suicide 6 months earlier - and the friend's parents. Also present was a local social educator.

The day after, a Thoughtful lecture was arranged for all students at her secondary school and for all parents at the school - for crisis management and to prevent transmission of suicidal ideation (suicide contagion). After the lecture a farther commented that *this was this most important knowledge he had ever heard on this school*.

Months later the social educator reported that the girl now read Thoughtful stories to friends who were in trouble - to help them cope with their situation and their dark thoughts.