Feasibility Test of the Treatment Program iACT-by Proxy - a Single Case Experimental Design

Background

Health anxiety by proxy is defined as parents' obsessive worries about their child's health(1). It is a newly described phenomenon, where the parent has persistent and distressing fears that his or her child may suffer from a serious disease that is being overlooked. These intrusive thoughts may lead to excessive attention directed towards their child's body and a tendency to interpret natural bodily sensations as unnatural and abnormal. As a consequence, parents with health anxiety by proxy may repetitively perform bodily inspections of their child (1, 2). Besides the stress related to worrying about your child's health, the condition can also cause frequent and unnecessary medical examinations of the child. As a possible consequence of this parental behavior, the child may be at risk of developing similar maladaptive illness behaviors, illness perceptions and illness worries(3).
Research on parents suffering from health anxiety has found evidence of health anxiety symptoms being transmitted from parent to child (4, 5) indicating that the parent's response to the child's health complaints (6) and how the parent copes with own symptoms may influence the health attitudes and behaviors of the child(7-10). This risk may be especially high if the parent suffers from health anxiety by proxy because the child is exposed to a particular preoccupation with and fear of illness and symptoms. For these reasons health anxiety by proxy is an important but neglected clinical phenomenon. Therefore, it is important to develop and test treatment targeting health anxiety by proxy. Other treatments have targeted the prevention of anxiety in children of anxious parents (11) and psychological treatments for health anxiety already exist as face-to-face or internet-based psychotherapy (12-14). However, the existing treatments do not specifically target health anxiety by proxy.

Internet-based treatment is a relatively new approach that compares favourably with face-to-face treatment as it is unrestrained by geographical distance and interferes less with daily life (15, 16). The Research Clinic for Functional Disorders and Psychosomatics, Aarhus University Hospital (AUH) has recently developed an internet-based treatment program (*iACT*) for health anxiety based on principles from Acceptance and Commitment Therapy (ACT)(17). This treatment has shown promising results (14, 18) and is used as a template for the development of specialised treatment for parents with health anxiety by proxy. The treatment is called iACT-by proxy and is targeting parents'

maladaptive anxiety-driven behaviour towards their child with focus on exposure therapy (gradually exposing yourself to the things that triggers the anxiety), but still in the context of ACT principles.

Overall aim

The aim of the study is to test the feasibility and possible effect of the iACT- by proxy treatment program for health anxiety by proxy using a single-case experimental design.

Hypotheses for single-case experimental design

- Patients will report a significant decrease in selected self-report measures of health anxiety by proxy answered every day when comparing the baseline period to the intervention period (Primary outcome).
- Patient self-report measures of health anxiety by proxy, emotional distress, and illness perception and catastrophizing when the child has symptoms will have decreased after intervention (Secondary outcomes).

Criteria for success of feasibility

- The treatment modules will be well received by the patients regarding format, length, content and contact to the therapist as measured by patient self-report on selected questions and with semi-structured interviews.
- Patients will log in to the modules on a weekly basis and will complete at least 6 out of 8 modules in the treatment. A module is complete when all text has been read in the module and corresponding exercises have been performed.
- Self-reported negative effects of participating are low.

Method

Participants

Participants in the study are parents assessed with health anxiety by proxy using the Health Anxiety by Proxy Scale (HAPYS). The HAPYS is currently undergoing validation. To separate severe health anxiety by proxy requiring treatment from milder conditions participants must score above the 75

% percentile based on the healthy population from the validation study. We are expecting 5 parents to participate in the study. A power calculation is not custom in the method used in this study(19)

Inclusion criteria

- Parents of age
- Assessed with severe health anxiety by proxy
- At least one child under 18 years
- Healthy children without severe hospital-treatment-requiring diagnoses or disabilities
- Read, write and speak Danish

Exclusion criteria

- Comorbid diagnoses of substance abuse, bipolar disorder, psychotic disorders (ICD-10: F20-29) or autism spectrum disorder.
- Recently starting up psychotropic drug (with-in the last two months)
- Suicidal risk

Recruitment

Participants with health anxiety by proxy self-refers to the project through the secured e-mail at the Research Clinic for Functional Disorders and Psychosomatics, AUH. After diagnostic video-interview they are included in the project.

Procedure for self-referral

Self-referral is a relatively new way of referring patients to treatment. It is used in the Internet psychiatry in the Region of Southern Denmark and was used at the Research Clinic for Functional Disorders and Psychosomatics during the iACT project(20). Further, it has been used in Stockholm for more than 10 years where more than 90 % of the patients is received through self-referral in their internet-psychiatric department. The method makes the access to treatment more easily available for the patients because the patients do not need to see their general practitioner to be referred.

In the current project the participants will find written information about health anxiety by proxy and the research project on the webpage. Participants apply for participation in the project by sending a secured e-mail containing their phone number to the Research Clinic for Functional Disorders and Psychosomatics. To increase the likelihood of the right participants self-referring to the project we plan to make a video with a patient suffering from health anxiety by proxy available on the webpage.

After e-mailing, the participant will receive a phone call from the investigator providing verbal information about the project. If the participant is further interested in the project he/she will be asked to provide their social security number (CPR) which will be entered into the secure web-based software platform for data collection REDCap (Research Electronic Data Capture) (23, 24). From REDCap a personalized link is sent to the participant's e-boks. Following the link the participant is met with written information about participation and a following statement of consent giving permission to the health professionals in the project to directly collect health information from the patient record and use questionnaire data for research purposes in anonymised form. NemID is accepted as a digital signature by the Data Protection Agency. After the statement of consent, the participant is redirected to a questionnaire about physical and psychological symptoms, and personal background information. If the questionnaire is complete and the consent is signed the participant is self-referred. The health-professional will now have direct access to the information in the patient record where information on former somatic and psychiatric illness, health care contacts and former examinations are necessary to support and qualify the diagnostic assessment only. The questionnaire information is stored on the treatment platform only accessible to the researchers, and the participant will be invited to a video-assessment through e-boks.

Assessment

All participants are assessed using a shorter standardised diagnostic interview based on SCAN (Schedules for Clinical Assessment in Neuropsychiatry (21)) and supplemented with assessment of health anxiety by proxy using the HAPYS. The passed information from the patient record concerning the patients' somatic and psychiatric health information is necessary supplementary information for conducting a thorough assessment. The diagnostic interviews will be conducted by SCAN-certified psychologists or medical doctors.

As part of the information provided at the self-referral the participant is informed about the importance of a finding a quiet and uninterrupted place during the video-interview. The interview is conducted using an encrypted link for a video-service hosted by the Central Denmark Region (rooms.rm.dk) which comply with the General Data Protection Regulation (GDPR). At the beginning of the interview, the health-professional ensures that the interview will be uninterrupted. The participant can have lay representative present during the interview if preferred. The assessment takes between 1-3 hours to complete which may entail inconvenience in terms of time spend and potential time off from work.

Before the interview the health-professional conducting the assessment provides verbal information about participation in the research project, and the participant can ask questions. The participants are informed that participation is voluntary and they may leave the study at any time without consequences for other treatments. After the interview the participant has two weeks to think about participation since the final consent is not given until the first login at the webpage.

Informed consent

All participants receive written and verbal information about the project. The participants receive the written information at self-referral. Verbal information is given at the phone call and again by the health-professional performing the diagnostic assessment at the Research Clinic for Functional Disorders and Psychosomatics, AUH (who is not necessarily part of the project group). They sign **two** consents; *one* when they complete the self-referral before the diagnostic interview, which gives the responsible investigators direct access to collect information from the electronic patient record for the purpose of using the participant's health information which is necessary for conducting the research project as well as for control purposes including self-regulation, quality-control and monitoring which they are obligated to conduct, and to use questionnaire data for research purposes in anonymised form; and *one* consent when entering the research project after the diagnostic assessment.

Signing the final consent the participants enters the project, gives permission to publish the research data, and gives permission to being contacted if they are absent from the treatment, if there is a

reasonable suspicious or if they have not filled in the questionnaires. In order to uphold the treatment responsibility, the participant provides a phone number of a relative in case of suicide suspicion. The system allows the participant to log out and log in again at a later time providing the participant with the opportunity to reflect before signing the consent. If the consent is not signed within two weeks after the interview the participant will be excluded from the study.

Design

The single-case experimental study will be designed with multiple baselines comparing the individuals' baseline level of health anxiety by proxy with the level of health anxiety by proxy during and following participation in the treatment (19, 22). In a multiple baseline design, the participants have different baseline lengths but the same intervention and follow-up period (see figure 1). The baseline and intervention period serves as two study conditions, a control (baseline) and a treatment condition (intervention) with N equally spaced measurement occasions(19). The baseline length is randomly assigned to the participants and serves as each participants' own control-condition. This makes it possible to have a small number of participants. If the intervention shows effect a change in the anxiety level will be detected during the intervention period.

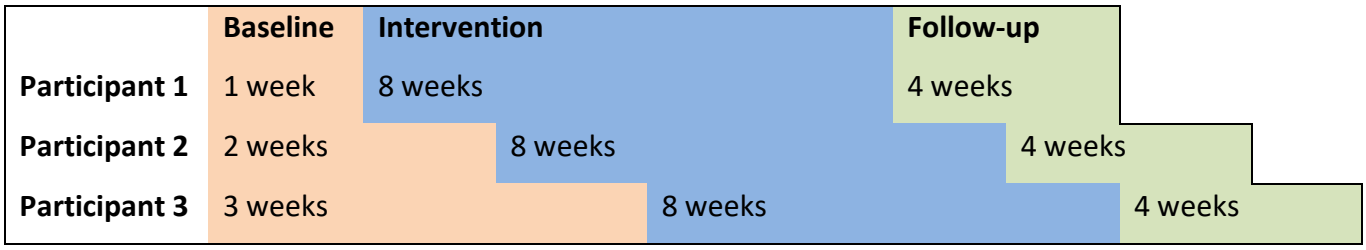

Figure 1 – example of varying baseline lengths

Measurements

All measures are self-report measures obtained through the secure web-based software platform for data collection REDCap (Research Electronic Data Capture)(23, 24) hosted at Aarhus University.

Assessment

- Short version of Schedules for Clinical Assessment in Neuropsychiatry (20, 21)

- The Health Anxiety by Proxy Scale (HAPYS) (Ingeman et al., submitted)

Primary outcome

The target measures of health anxiety by proxy are answered though a link in a SMS to the participants every day from start of baseline to end of follow-up. The order of the items will be random each day. The target measures contain items of core characteristics of health anxiety by proxy which have been selected from the HAPYS based on the following:

1) Items that has excellent face validity.

2) Items with indicative high sensitivity to change.

Face validity was investigated by experts within the field of health anxiety assessing each item in the HAPYS for characteristics of health anxiety by proxy. This was supplemented by statistical analyses investigating sensitivity to change on the Whiteley-8 Index. The Whiteley-8 index is a measure of health anxiety, but contains items with similar wording and content as the HAPYS since HAPYS was developed with inspiration from the Whiteley Index. Ensuring that the items used to measure health anxiety by proxy are sensitive to change is highly important in a single-case design because if the treatment has an effect it will be crucial to be able to see it in the small sample. Items are adapted to fit statements about present day.

Secondary outcome

Standardised self-report questionnaires will be answered four times during the study period (before baseline, right before treatment entry (end of baseline), end of treatment, and at 4-weeks follow-up. These are:

- The health anxiety by proxy scale (HAPYS) (Ingeman et al., submitted)
- The Adult Response to Children's Symptoms (ARCS) – parent form (revised) (2, 25)
- Pain Catastrophizing Scale – parent version (PCS-P) (26, 27)
- The Whiteley-6 Index(28)
- SCL-8 (emotional distress) (29, 30)
- WHO-5 Well-Being Index (31)

Feasibility outcome

Participants are asked to provide feedback on format, length and content of the treatment program as well as on the contact to the therapist after each treatment-module and in a semi-structured phone-interview with the Ph.D.-student after treatment end.

Only answered at end of treatment:

- Experience of Service Questionnaire (ESQ) (32) – modified to internet-based treatment
- The Negative Effects Questionnaire - 20 (NEQ) (33)
- Internet Evaluation and Utility Questionnaire (IEUQ) – modified (34)
- Evaluation of the method for SMS-gathered data

QUESTIONNAIRE ANSWARED	EVERY OTHER DAY	ONCE A WEEK	BASELINE	END OF BASELINE	END OF TREATMENT	FOLLOW-UP
SELECTED ITEMS FROM HAPYS	X					
HAPYS			X	X	X	X
WHITELEY-6			X	X	X	X
SCL-8			X	X	X	X
ARCS			X	X	X	X
PCS-P			X	X	X	X
WHO-5			X	X	X	X
ESQ					X	
NEQ					X	
IEUQ					X	
SMS-EVALUATION					X	
FEASIBILITY MEASURES		X			X	
SUICIED RISK		X				

Intervention

The treatment is an eight-week therapist-supported internet-based program based on written psychoeducation, audio-files, behavioural exposure exercises, homework and videos distributed in eight short modules.

Data analysis

Analysis will be divided into primary outcome and secondary outcome. The primary outcome will be analysed using visual analysis of plotting data and observing if the measures decreases at time of intervention entry (19). Further, using a Bayesian analysis of clinically significant change will quantify the evidence for the size and presence of an intervention effect (35, 36). The secondary outcome is analysed by determining Jacobsen's Reliable Change Index and from this determine that the change seen is not at result of measurement error and whether it is clinically significant(19, 37). The online free-text-answers and the interview on formalities and contact to therapist will be explored using thematic analysis focusing on all participant-experiences.

Funding

The Ph.D.-student and the Department of Child and Adolescent Psychiatry has initiated the research project in collaboration with the Research Clinic for Functional Disorders and Psychosomatics, AUH and received funding from numerous funds:

450.000 kr. Aarhus University grant
407.652 kr. The Health Research Fund of Central Denmark Region 2019
280.393 kr. The Health Research Fund of Central Denmark Region 2018
159.726 kr. The Department of Child and Adolescent Psychiatry, Research Unit, AUH

The funding is spread over the entire PhD project and not only used for this particular experiment. The means mainly cover salary for the PhD student. All funding is administered by the Department of Child and Adolescent Psychiatry, AUH and the researchers have no affiliation to the funds.

Ethics

There are no expected side effects or risks in participating in this study. The project is conducted in accordance to the rules in the Helsinki-Declaration. The project is registered under the Central Denmark Region's records of research projects (*Den interne fortegnelse over forskningsprojekter ved Region Midt*; 1-16-02-921-17) and it will be reported to the international database for clinical trials (clinicaltrials.gov).

Adverse effects, risks and benefits

There is no previous research data suggesting that internet-based treatment for health anxiety, anxiety or depression are associated with any form of risk (12, 14-16, 18). It is expected that participation in the treatment will improve the participants' anxiety symptoms and improve their quality of life. Further, the treatment may prevent transmission of maladaptive illness perception and illness behaviour from the parent to the child which may otherwise be a risk factor for child development of health anxiety symptoms and functional disorders (6, 8-10, 38, 39).

Participants are asked about suicidality each week with the question:" Thoughts about ending your life". If the score is 3 or above (likert-scale 1-5) a global message will be sent to all therapists informing that there is a suicidal risk. The global message will ensure fast act on the risk by telephone screening.

The participants are asked about prospective negative effects after end treatment like deterioration, lack of trust in the treatment and therapist, sleep problems, negative thinking and unpleasant feelings like hopelessness and sadness etc.

Currently there is no available treatment offers for parents with health anxiety by proxy even though it is a very debilitating condition and may further influence the children of these parents if left untreated. The internet-based format will make this treatment available for patients who live far from specialized clinics and who are interested in a format that interferes less with daily life.

Data protection

All information concerning the participants is protected by the data protection act and the data protection regulation. All personal data including name, telephone number and social security number is encrypted. The questionnaires are not personally identifiable, but have a random ID-number. The participants provide written informed consent to publish data in a single-case format where each participant's data is reported separately, but anonymized.

The platform hosting the treatment program was developed and programmed at the Research Clinic for Functional Disorders and Psychosomatics. The platform (internetbehandling.dk) utilizes the Drupal Content Management System (CMS) as a framework. That is, the user creation, login procedure, storing of data in database fields and so on are controlled by the standard modules and components built into the CMS. The custom functionality is written as Drupal plugins in object-oriented PHP making it easy to flexibly update and replace parts of the system when necessary. All access to the server goes through an encrypted SSL-connection, and data pooling is being logged with IP and user-ID. NemID is used to log in to the platform. Access to the questionnaire data is only granted to researchers in the project and the data will be kept anonymously after project-end.

The patients are covered by the act on the right to complain and receive compensation because they are registered as patients at the Research Clinic for Functional Disorders and Psychosomatics, AUH.

Results

Both positive, negative and inconclusive results from the project will be published in peer-reviewed journals and the guidelines for good scientific practice will be followed (22).

Project group

The project is conducted at the Research Clinic for Functional Disorders and Psychosomatics who possesses the treatment responsibility in collaboration with the Department of Child and Adolescent Psychiatry, AUH who is in responsible for project management and data analysis. The project

group consist of Katrine Ingeman Beck, psychologist (PhD student)[1,2], Charlotte Ulrikka Rask, MD, professor, PhD[1,2] (Main supervisor); Lisbeth Frostholm, head psychologist, associate professor, PhD[3,2] (Co-supervisor); Kristi Wright, psychologist, associate professor, PhD[4] (Co-supervisor); Ditte Hoffmann Jensen, psychologist, PhD[3] (Co-supervisor); Nicolaj Knudsen, web and software developer[3].

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