This protocol is structured in accordance with the CONSORT – statement for Randomized Controlled Trials with the extension for Non-Pharmacological Treatment Interventions, http://www.consort-statement.org/home/. Protocol sections are shown below each CONSORT item.

# Research Protocol

August 2014

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| CONSORT – Statement (CON) | Non-Pharmacological Treatment Interventions (NPT) |
|---|---|
| **Title and abstract** | |
| **1a** Identification as a randomized trial in the title.<br>**1b** Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts). | In the abstract, description of the experimental treatment, comparator, care providers, centers, and blinding status. |

# Resilience for young people with ADHD – a survey and a randomized controlled trial of a Brief Intervention Program.

## Content

## Dansk Resume

Unge med ADHD er i en udsat livssituation med forøget risiko for stress samt fysiske og psykiske helbredsproblemer og sociale problemer senere i livet.

I nærværende projekt inviteres unge voksne ADHD patienter (18-27 årige) i Danmark samt en tilfældig stikprøve af 18-27 årige til at medvirke i en spørgeskemaundersøgelse, hvor de får mulighed for at fortælle om, hvordan de har. Deltagere inviteres på grundlag af et dataudtræk fra Landspatientregisteret.

Formålet med spørgeskemaundersøgelsen er at bidrage med viden, som forhåbentlig kan være med til at forbedre hverdagen for unge med ADHD og unge i al almindelighed.

I forbindelse med spørgeskemaundersøgelsen tilbydes halvdelen af deltagerne adgang til et nyt videns- og inspirationsprogram om robusthed kaldet Robusthed.dk. Robusthed handler om at blive god til at klare dagens udfordringer i stort og småt - *især når livet er svært*. Robusthed kan blandt andet bruges til at gøre det nemmere at lære, træffe gode beslutninger og forebygge stress & konflikter. Omfattende pilotundersøgelser af Robusthed.dk programmet tyder på, at det har bred anvendelighed og er effektivt. I et pilotforsøg i et svært belastet miljø, er hyppigheden af høj-risiko konflikter reduceret med mere end 90 %.

1 år senere inviteres alle deltagere til igen at besvare de samme spørgsmål. Disse data sammenlignes med baseline data og er grundlag for vurderingen af Robusthed.dk programmets eventuelle effekter. Via registerdata vurderes desuden effekter i forhold til læring og uddannelse.

# Background

## The Child Mental Health Research Program and the intervention program Robusthed.dk

| CONSORT – Statement (CON) | Non-Pharmacological Treatment Interventions (NPT) |
|---|---|
| **Introduction - Background and objectives** | |
| **2a** Scientific background and explanation of rationale.<br>**2b** Specific objectives or hypotheses. | |

The Child Mental Health Research Program has been started by Tryg Foundation grants in 2012 and 2013 with the purpose of establishing high quality research projects.

The goals of the research program are:

1. To develop and test health care models which can strengthen the clinical and educational support of vulnerable children, families and surrounding professionals – facing the serious welfare challenges of today's society. This includes the integration of information about the child's strengths and difficulties with tailored interventions.
2. To elucidate early life causal patterns and consequences for long term mental and somatic health and integrate this knowledge in the support and intervention models.

The research program is organized in cooperation between Aarhus University and Region Midt. A description of the organization and the six integrated Work Packages of the program (WP1-6) can be found at the research program website (link).

The current project concerns a coherent brief intervention program (Work Package 4: Step care interventions) which has now been developed and is ready for testing in controlled trials with a number of different target groups.

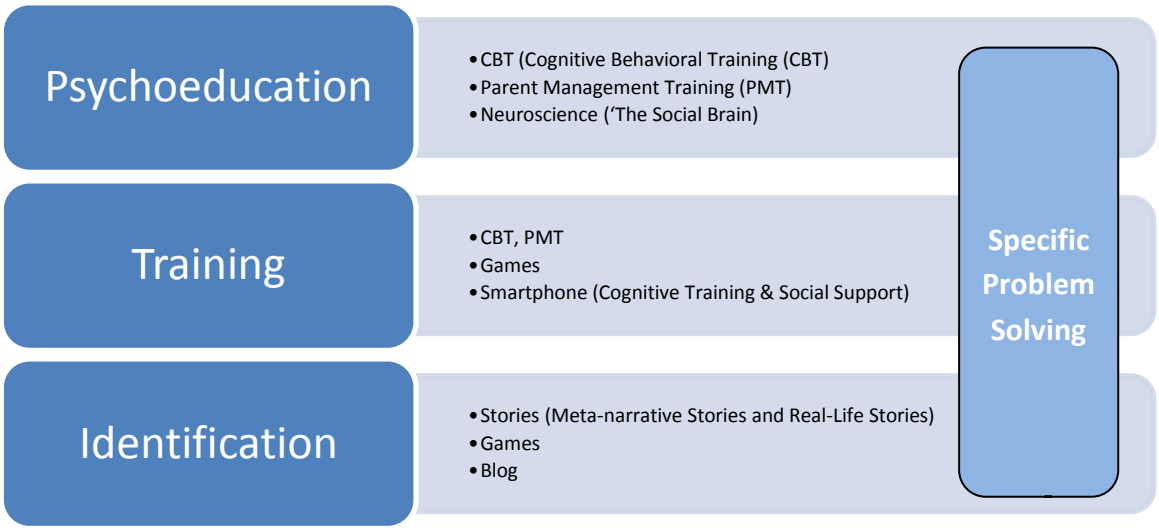
The intervention program is designed to respond to calls to exploit low cost & large scale intervention delivery models expressed by for instance Professor Allan Kadzin (Kadzin & Blasé 2011) and Professors Anthony Roth and Peter Fonagy (Roth and Fonagy 2006). The idea is to meet the socio-economic pressure on the public welfare sector concerning mental health which is currently a considerable challenge in many countries (Foresight Mental Capital and Wellbeing Project 2008). At present the principal suggested support model for mentally vulnerable individuals and families consist of advice and training on individual, family and group basis by trained professionals. These are, however, resource demanding models of delivery which society has a hard time to honor. The situation speaks for the development and testing of more resource efficient models to supplement these traditional models. Cochrane reviews suggest that self-directed media and internet based intervention programs may be as effective as traditional models of delivery (Montgomery, Bjornstad & Dennis 2006). In some respects contemporary and future internet based programs is expected to be superior to the traditional models of delivery (O'Connell 2009, Perkins et al 2009). However, much more rigorous research is needed in the field.

The intervention program in this research project is called Robusthed.dk (Robusthed is the Danish word for Resilience) because the program is designed to support resilience development in mentally vulnerable children, young people and families in cooperation between professionals and parents. The program is designed to meet different levels of difficulties (with or without diagnoses) and can also be used in general health promotion, conflict management and prevention of bullying.

Children and adolescents needs to develop resilience in order to handle the challenges of life, small as well as big ones – especially when being in a vulnerable position. Self-control and Self-regulation are important parts of being resilient. Self-control in childhood is a strong predictor for health, wellbeing and social behavior later in life (Moffit 2011). Self-control is specifically addressed in the intervention program.

The program is web based and includes documented knowledge available from cognitive- and neuroscience ('The Social Brain') as well as established experiences from parent training programs and social learning research in line with the NICE guidelines (NICE 2008, 2009). This is transformed into simple coherent presentations in daily language – equally understandable for a student, a parent and a highly educated professional. The program exploits the opportunities of contemporary information technology including animations, podcasts and smartphone application for cognitive training and social support.

From a theoretical point of view the program is structured in 3 dimensions – which are coupled to specific problem solving from a list of 12 important types of life problems (e.g. conflict & bullying, anxiety, sadness, sleep, acute crisis, pain, dependency, learning difficulties, etc.):




A detailed review of the scientific background of the program is found on the English version of the Robusthed.dk website http://myresilience.org/ (on the sub-site "About Us").

Results published in 2012 from a related uncontrolled precursor project in which central elements from the current program was included (involving about 4000 teachers and preschool teachers working with children, young people and families and 3000 parents) has demonstrated wide applicability and a high feasibility (Lundgaard Bak 2012).

The program can be tested on www.Robusthed.dk (The program is in Danish, English and Greenlandish).

In the intervention projects, all participants are offered exactly the same background knowledge and practical knowledge of how resilience training can be integrated in daily life. The program is introduced for the target groups in standardized short lectures and courses and participants are given a trial-specific login to the program website.

The trials in the research projects are designed to follow the 'Recommendation on Criteria for Establishing Strong Evidence of Effectiveness' from The National Academies report: Preventing Mental, Emotional, and Behavioral Disorders among Young People: Progress and Possibilities (O'Connell 2009).

It is reasonable to assume that resilience is valuable for human beings in almost any context. Therefore it is relevant to investigate the eventual impact of the intervention program in a range of different contexts.

Thus the aim is to investigate - with societal relevant primary outcome indicators - if the brief intervention program Robusthed.dk can have a significant positive impact on the lives of selected target groups of vulnerable children, young people and families. The target groups have been selected on the basis of the following criteria:

- Relevance with respect to problem severity and/or scale in society
- Representation of different age groups
- Representation of different organizational contexts
- Exploiting synergies in the Child Mental Health Research Program (see www.iupgrowth.com).
- Exploiting the opportunities of using administrative (register) data as outcome indicators as recommended by the Coalition for Evidence Based Policy (2012): *How Low-Cost Randomized Controlled Trials Are Possible in Many Areas of Social Policy.*

4 large scaled trials are started in 2013-14 – covering children and adolescents in care (0-18 year), school projects (6-17 year), youth education (15-25 year) and ADHD (15-25 year). Moreover, a suicide prevention study is started in Greenland in 2013. **This protocol concerns the ADHD trial**.

Table 1: Target groups in current and future research projects.

| Age: | Pregnancy | 0-5 year | 6-17 year | 18-25 year |
|---|---|---|---|---|
| DK Interventions in current trials | | | | |
| Robusthed.dk | | Children and adolescents in care | | |
| | | | School intervention | |
| | | | | Youth Education |
| | | | | ADHD |
| DK interventions covered by future Danish applications | | | | |
| Robusthed.dk | Stress | Young mothers | | |
| International interventions covered by international applications | | | | |
| Robusthed.dk | | | Greenland: Suicide prevention (the project starts autumn 2013) | |
| | | | EU- mental disorder | |

## The ADHD Trial

Children and young people with ADHD are in a vulnerable position in life. Their health risks and social risks in life are increased.

The prevalence of ADHD among children is 3-5 % (Ford, Goodman & Meltzer 2003, Polanczyk et al 2007). In Denmark as well as in other countries the incidence has been increasing during several decades (Atladottir et al 2007).

More than 85 % has one comorbid condition and 60 % has two or more such as behavioral disorder, depression, anxiety and learning difficulties (Brown, Freeman & Perrin 2001). Behavioral disorder is most frequent. Even though the neurological basis for ADHD is rather well understood (Castellanos, Lee & Sharp 2002) the clinical presentation is heterogeneous (Thapar et al 2012, Wilens 2007). Subclinical ADHD also affects learning and education negatively (Rodriguez et al 2007) - even for class mates (Atkins & Pelham 1991).

ADHD is most frequently diagnosed among boys (Ullebø et al 2011, Arnold 1996). The reason may be that the frequency of ADHD among boys may be genuinely larger than among girls or may be boys simply have more outwardly symptoms (Biederman, Mick & Faraone 2002).

50-75% of children and adolescents with ADHD will also have problems as adults (Kessler, Adler & Barkley 2006) - with increased risk of asocial behavior, drug addiction, unemployment and social relation problems (Spencer, Biederman & Mick 2007). However our knowledge about ADHD and treatment in a long life perspective is still limited (Cumyn et al 2007).

A number of ADHD training programs have been developed in the last 30 years – especially in USA – and mostly for families with ADHD children. Program effects are generally positive and guidelines for this kind of programs have been developed (NICE 2007, 2008). Programs for broader target groups than ADHD have also been developed – e.g. The Incredible Years and Triple-P (O'Connell 2009, Montgomery, Bjornstad & Dennis, 2006, Prinz et al 2009). The Danish National Board of Social Services (Servicestyrelsen) has recommended a number of the programs (Servicestyrelsen 2012).

Program effects are limited in case of comorbidity and low attrition (Eames et al 2008, 2009, 2010, Sonuga-Barke 2002, 2004). The programs are developed and tested for limited age groups and the evidence is often based on small and rather old studies in highly selected populations. No one knows if results can be generalized to populations in other countries (Furlong 2012). Moreover, the programs are resource demanding which is especially a challenge in hard times.

It seems likely that programs that are more flexible can increase the effect (Weisz et al 2012) and there is a general need to develop a new generation of so-called low cost brief intervention programs. They must build on existing knowledge, at the same time be more flexible and exploit the opportunities of new technology (Kazdin & Blasé 2011, Montgomery, Bjornstad & Dennis 2006, O'Connell 2009). It must be possible to use the programs efficiently on a large scale by families, young people and adults with or without cooperation with professionals – both as an early intervention and in grave situations. At the same time, the programs must be useful in complex comorbid conditions.

These are some of the reasons why there is increasing focus on working with resilience (Reich, Zautra & Hall 2010, Ager 2012). Resilience is about coping with challenges in life. Having ADHD and being together with a person with ADHD can be challenging on many levels. So there is good reason to investigate if it possible to support the development of resilience among young people with ADHD with contemporary programs – such as the current Resilience Program 'Robusthed.dk'.

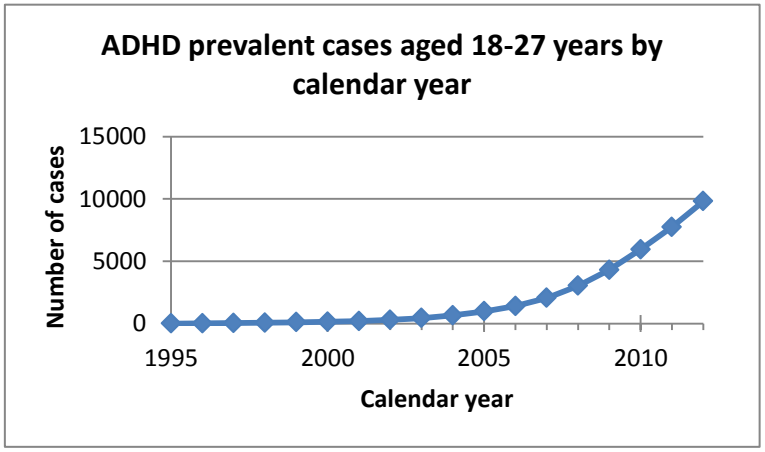
## Trial design & intervention

| CONSORT – Statement (CON) | Non-Pharmacological Treatment Interventions (NPT) |
|---|---|
| **Methods – Trial Design** | |
| **3a** Description of trial design (such as parallel, factorial) including allocation ratio.<br>**3b** Important changes to methods after trial commencement (such as eligibility criteria), with reasons. | |

| CONSORT – Statement (CON) | Non-Pharmacological Treatment Interventions (NPT) |
|---|---|
| **Methods – Interventions** | |
| **5** The interventions for each group with sufficient details to allow replication, including how and when they were actually administered. | **4** Precise details of both the experimental treatment and comparator.<br>**4a** Description of the different components of the interventions and, when applicable, descriptions of the procedure for tailoring t d he interventions to individual participants.<br>**4b** Details of how the interventions were standardized.<br>**4c** Details of how adherence of care providers with the protocol was assessed or enhanced. |

This is a randomized controlled trial with a Non-Pharmacological Treatment Intervention (NPT). No methods (such as eligibility criteria) will be changed after trial commencement.

Patients age 18-27 with ADHD diagnosis registered in the Danish National Patient Register will be identified. (Approved by the Danish Data Protection Agency and the Danish National Board of Health). Based on data from the central Psychiatry Register this is estimated to be about 10.000 persons:



Individuals who have requested legal protection against contacts from researchers (about 20 % of the population in this age group) are not included in the study.

The study population is randomized by a computer program (STATA) into a control group and an intervention group of same size:

| Study population | Intervention group | Control group |
|---|---|---|
| ADHD population | 4000 | 4000 |

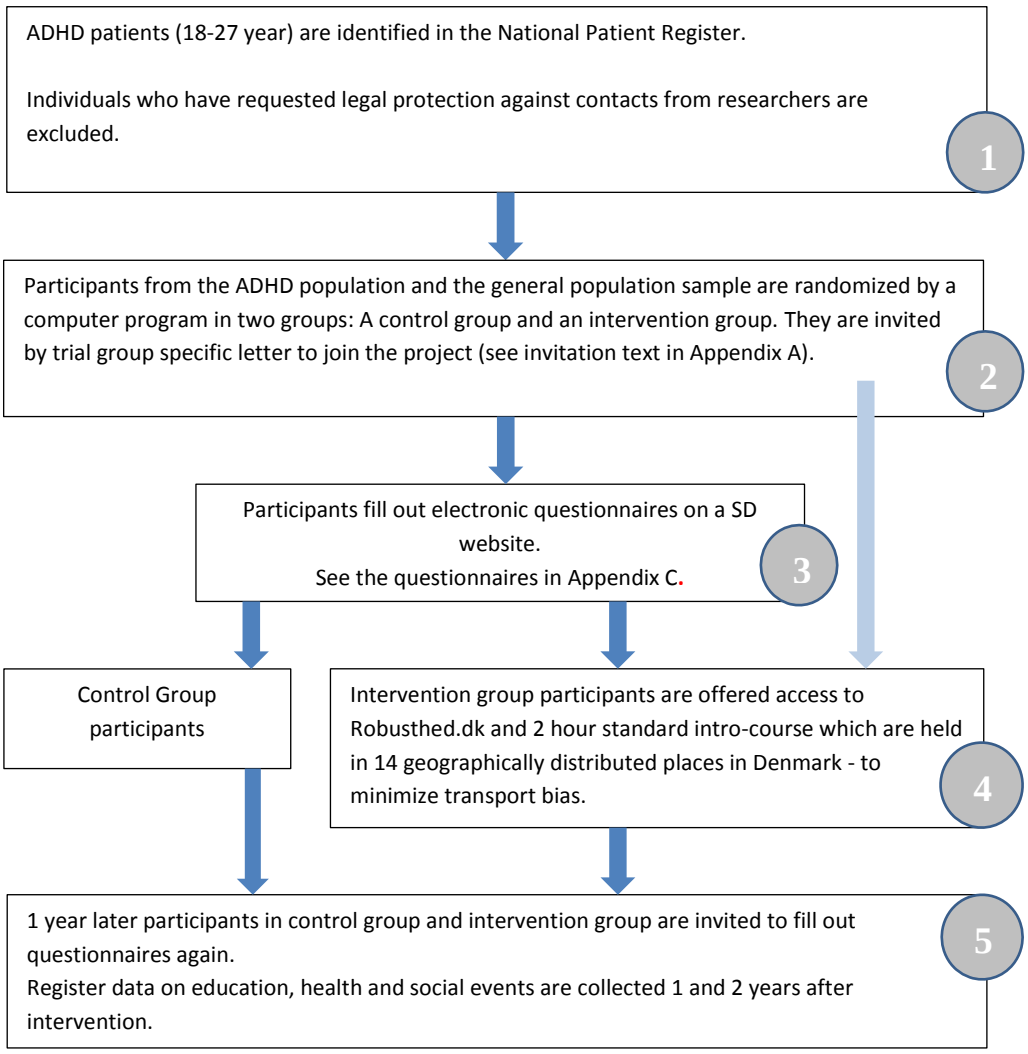
The CPR numbers (the Danish personal identification number) of the individuals in the selected ADHD population are linked to the CPR register for address identification. Trial group specific invitations to join the project are send by letter from DS to all individuals in the study population (See invitation text in appendix A).

Invited persons log in with a unique code and password on a project website and answer the electronic questionnaires (see appendix B).

Intervention group participants are offered access to Robusthed.dk and 2 hour standard intro-course which is held in 14 geographically distributed places in Denmark - to minimize transport bias.

1 year later all participants in control group and intervention group are invited to fill out questionnaires again. Register data on education, health and social events are collected 1 and 2 years after intervention.

Trial design and data flow is shown in this diagram:



## Participant eligibility

| CONSORT – Statement (CON) | Non-Pharmacological Treatment Interventions (NPT) |
|---|---|
| **Methods - Participants** | |
| 4a Eligibility criteria for participants.<br>4b Settings and locations where the data were collected. | **3** When applicable, eligibility criteria for centers and those performing the interventions. |

Eligibility criteria:

- Patients age 18-27 with ADHD diagnosis registered in the Danish National Patient Register.
- No request for legal protection against contacts from researchers.

## Outcome measures

| CONSORT – Statement (CON) | Non-Pharmacological Treatment Interventions (NPT) |
|---|---|
| **Methods - Outcomes** | |
| **6a** Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed.<br>**6b** Any changes to trial outcomes after the trial commenced, with reasons. | |

Outcome measures in the study are based on the following data sources:

- Questionnaire data from participants before and 1 year after intervention.
- Register data on education, health and social events.

No trial outcome measures will be changed after trial commencement.

Primary outcome measure will be change in ASRS score (Arngrim et al 2013).

Secondary outcome measures will be

- Change in GHQ12 score (before/after intervention) (Goldberg et al 1997) – using Lickert scoring.
- Youth Education attrition (register data)
- Health data: medication and use of health care services (register data)
- Social events such as criminal incidents (register data).

We expect the primary and secondary outcomes to be normal distributed, or approximately after transformation (Z-score or log-transformation). The means and the standard deviations will be presented. The effect estimates of intervention will be calculated by comparing the intervention group with the control group. Intention to treat analysis will be the basic principle. Naturally it is not expected that 100 % will answer the questionnaires but the register data are expected to be nearly complete.

Separate analyses will be conducted for the different age and recruitment groups.

## Sample size calculations

| CONSORT – Statement (CON) | Non-Pharmacological Treatment Interventions (NPT) |
|---|---|
| **Methods – Sample Size** | |
| **7a** How sample size was determined.<br>**7b** When applicable, explanation of any interim analyses and stopping guidelines. | When applicable, details of whether and how the clustering by care providers or centers was addressed. |

The distribution of GHQ-12 scores in a Danish ADHD population is unknown.

Based on a conservative power calculation from the magnitude of abnormal SDQ[1] score among young people we estimate that we need at least 800 participants in the control group and 800 in the intervention group.

Based on the eligibility criteria we estimate that our study population potentially will comprise about 8.000 individuals which are well above the required minimum.

[1] The Strength and Difficulties Questionnaire (SDQ) is a validated international questionnaire often used in screening of children and young people with ADHD.

## Randomization

| CONSORT – Statement (CON) | Non-Pharmacological Treatment Interventions (NPT) |
|---|---|
| **Methods – Randomization – sequence generation** | |
| **8a** Method used to generate the random allocation sequence.<br>**8b** Type of randomization; details of any restriction (such as blocking and block size) | When applicable, how care providers were allocated to each trial group. |

| CONSORT – Statement (CON) | Non-Pharmacological Treatment Interventions (NPT) |
|---|---|
| **Methods – Randomization – Allocation concealment mechanism** | |
| **9** Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned. | |

| CONSORT – Statement (CON) | Non-Pharmacological Treatment Interventions (NPT) |
|---|---|
| **Methods – Randomization - implementation** | |
| **10** Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions? | |

| CONSORT – Statement (CON) | Non-Pharmacological Treatment Interventions (NPT) |
|---|---|
| **Methods - Blinding** | |
| **11a** If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how.<br>**11b** If relevant, description of the similarity of interventions. | **11a** Whether or not those administering co-interventions were blinded to group assignment.<br>**11b** If blinded, method of blinding and description of the similarity of interventions. |

As mentioned above randomization will be done automatically by a computer program (STATA). There will be no restrictions to the randomization. There will be no personal or electronic contacts between participants and researchers. The professionals running the Resilience intro-courses in the intervention group works independently from the researchers. All outcome data are collected electronically and automatically without any contact between participants and researchers.

## Statistical methods

| CONSORT – Statement (CON) | Non-Pharmacological Treatment Interventions (NPT) |
|---|---|
| **Methods - Statistical methods** | |
| **12a** Statistical methods used to compare groups for primary and secondary outcomes.<br>**12b** Methods for additional analyses, such as subgroup analyses and adjusted analyses. | When applicable, details of whether and how the clustering by care providers or centers was addressed. |

Linear and logistic regression models will respectively be used to estimate the impact of the interventions on the continuous variables of the primary or secondary outcomes. The analyses will take into consideration a few covariates available at baseline, including sex, age, and recruitment population. Intention to treat analyses will be applied to the primary outcomes, as the registers have information on almost all participants.

## Time table

| | 2013 | | 2014 | | 2015 | | 2016 | | 2017 | |
|---|---|---|---|---|---|---|---|---|---|---|
| Prepare trial and recruit participants | | | | | | | | | | |
| Intervention | | | | | | | | | | |
| Follow up and data collection | | | | | | | | | | |
| Data analysis and publication | | | | | | | | | | |

## Ethical and legal consideration

- The Ethical Committee has stated that Committee approval for this trial is not needed.
- The trial has been approved by the Ministry of Children and Education.
- The Trial has been approved by the Danish Data Protection Agency.
- The Trial has been approved by the the National Board of Health.

This trial follows the CONSORT – statement criteria including the extension for Non-pharmacological Treatment Interventions.

Information to participants: See appendix A.

The control group continues “Service/Treatment As Usual”. Being in the control group does not restrict their actions or services in any way.

The intervention Robusthed.dk consists of the dissemination of scientifically based knowledge and inspiration for reflection and conversations in daily life. The specific use of the elements in the program is tailored by the participants and the relatives and professionals around the young people. No participants in the intervention or control groups are prevented from receiving any kind of service as usual as a result of the trial.

Any participant can at any time abstain from participation in the survey and also the intervention part of the project.

## Project Feasibility

The intervention program has been specifically designed as a low cost brief intervention program for large scale use. Trial size has been dimensioned to fit with this design and also on the basis of experiences from similar earlier projects (Lundgaard Bak 2012) and pilot experiences.

## Qualifications of the research group

The research group has a long experience in primary and public health care work and science –especially within clinical epidemiology and practical method development, evaluation and implementation. For detailed information please refer to the CV's and the Research Program website http://iupgrowth.au.dk/ .

Child Mental Health Research Program responsible: Associate professor Phd Carsten Obel
Robusthed.dk trial responsible: Poul Lundgaard Bak, MD
Data-analysis: Jin Liang Zhu, MD

## Publication

Results will be published in peer-reviewed journals, at national and international conferences and national media as well as on the research program website. Publication will follow the CONSORT guidelines as described in this protocol. The CONSORT items which pertain to result presentation and discussion in the publications are shown in Appendix D.

## Scientific Perspectives

We believe that the intervention project will contribute with knowledge about whether it is possible to support young people with ADHD on a large scale with low cost programs using contemporary knowledge and technologies.

## Practical perspectives, knowledge dissemination

The current program has specifically been designed for easy and low cost implementation. If relevant positive effects can be demonstrated we will recommend starting nationwide implementation via conferences arranged in collaboration with the key partner organizations in the project**.**

On a national level it is estimated that 1-2 consultants per municipality can implement the program adequately in a community wide setting (therapeutic settings, care settings as well as public school settings) - on a part time basis integrated as a part of their job portfolio. Using professionals employed in the municipalities as consultants will ensure ownership and anchor the program in the organizations. Based on previous experiences (Lundgaard Bak 2012) it is estimated that 10 day training (including basic course +

follow up) is sufficient for a consultant to achieve competency for local implementation. It means that if training courses is held in the 5 regions of the country, implementation can be started on a national scale within ½-1 year after completion of the research project – provided of course that the research results documents that it is worthwhile to implement the program on a larger scale and resources for training of consultants are available.

In case of sufficient positive effects there will of course also be permanent open access to the website.

## Trial registration

This trial will be registered in ClinicalTrials.gov.

## Protocol access

| CONSORT – Statement (CON) | Non-Pharmacological Treatment Interventions (NPT) |
|---|---|
| **Other information - protocol** | |
| **24** Where the full trial protocol can be accessed, if available. | |

The trial protocol is available at http://myresilience.org/ at the subsite “about us”.

## Funding

| CONSORT – Statement (CON) | Non-Pharmacological Treatment Interventions (NPT) |
|---|---|
| **Other information -** | |
| **25** Sources of funding and other support (such as supply of drugs), role of funders. | |

This trial has been funded by The Tryg Foundation.

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## Appendix A: Invitation (letter) to join the project (in Danish):

# Invitation til en undersøgelse blandt 18-27 årige

Vi skriver til dig, fordi du på et tidspunkt har fået diagnosen ADHD. Vi vil gerne vide mere om, hvordan unge med ADHD trives.

Din deltagelse er selvfølgelig frivillig, men det vil være af stor betydning, at du deltager. Den viden, du er med til at give, er meget vigtig i forhold til at blive klogere på, hvordan vi bedst hjælper dig og andre unge med disse problemer.

Du deltager i undersøgelsen ved at besvare et kort spørgeskema nu og om et år. Det tager normalt få minutter, og vi behandler selvfølgelig dine svar strengt fortroligt, og deler dem ikke med andre. Vi er ikke interesserede i de enkelte deltageres svar og ser kun på resultaterne på gruppeniveau.

Vi vil bede dig logge dig ind på hjemmesiden **www.ungADHD.dk** med
Nøgle: **51244**
Kode: **TSECN**

**Brevet til deltagerne i forsøgsgruppen indeholder desuden følgende afsnit:**

Vi har udviklet et nyt videns-program, som du kan finde på **www.robusthed.dk** . Vi vil gerne tilbyde dig at prøve dette program, da vores erfaringer er, at det kan være en hjælp i hverdagen, især for unge med særlige udfordringer, som du måske har.

Robusthed handler især om balancen mellem tanker og følelser. På siden kan du finde inspiration til løsning af problemer og mulighed for at træne via app på din smartphone.

Vi tilbyder dig desuden at deltage i et arrangement, hvor vi fortæller om **Robusthed**. Vi ved fra andre unge, som har været med, at de synes, det er vildt spændende og meget relevant.
På **www.Robusthed.dk/foredrag** kan du se, hvornår vi afholder et arrangement tæt på, hvor du bor.
Det er gratis, og der er ingen tilmelding.
Du er også velkommen til at invitere et par venner/familie med.

Venlig hilsen
Læge Carsten Obel og læge Poul Lundgaard Bak
Institut for Folkesundhed
Aarhus Universitet

**Kontaktperson: Læge Poul Lundgaard Bak** plb@ph.au.dk

Undersøgelsen er støttet af SATS-pulje midler.

## Appendix B:

## Questionnaire (in Danish):

| | |
|---|---|
| Får du ADHD medicin? | Ja/Nej |
| Går du til psykolog samtaler? | Ja/Nej |

| **ASRS 6. I de sidste 6 måneder** | | | | | |
|---|---|---|---|---|---|
| | Aldrig | Sjældent | Nogle gange | Ofte | Meget ofte |
| Hvor ofte har du svært ved at afslutte et projekt og få de sidste detaljer på plads, når den udfordrende del af arbejdet er overstået? | | | | | |
| Hvor ofte har du svært ved at klare en opgave, der kræver planlægning? | | | | | |
| Hvor ofte har du problemer med at huske aftaler eller andet, du burde huske? | | | | | |
| Hvor ofte undgår eller udsætter du en opgave, som kræver mange overvejelser? | | | | | |
| Hvor ofte sidder du uroligt med hænder og fødder, når du skal sidde ned i længere tid? | | | | | |
| Hvor ofte føler du dig overaktiv og nødt til at gøre ting, som var du drevet af en indre motor? | | | | | |

| **GHQ-12. Har du i den sidste måned:** | | | | |
|---|---|---|---|---|
| 1. Kunnet koncentrere dig om det, du er i gang med? | Bedre end sædvanligt | Det samme som sædvanligt | Dårligere end sædvanligt | Meget dårligere end sædvanligt |
| 2. Mistet søvn på grund af bekymringer? | Nej slet ikke | Ikke mere end sædvanligt | Noget mere end sædvanligt | Meget mere end sædvanligt |
| 3. Følt at du spiller en nyttig rolle i det daglige? | Mere end sædvanligt | Det samme som sædvanligt | Mindre nyttig end sædvanligt | Meget mindre nyttig end sædvanligt |
| 4. Følt at du har været i stand til at tage beslutninger? | Bedre end sædvanligt | Det samme som sædvanligt | Mindre end sædvanligt | Meget mindre end sædvanligt |
| 5. Følt dig konstant under pres? | Nej slet ikke | Ikke mere end sædvanligt | Noget mere end sædvanligt | Meget mere end sædvanligt |
| 6. Følt at det var svært at klare dine vanskeligheder? | Nej slet ikke | Ikke mere end sædvanligt | Noget mere end sædvanligt | Meget mere end sædvanligt |
| 7. Været i stand til at nyde dine normale daglige aktiviteter? | Mere end sædvanligt | Det samme som sædvanligt | Mindre end sædvanligt | Meget mindre end sædvanligt |
| 8. Været i stand til at se dine problemer i øjnene? | Mere end sædvanligt | Det samme som sædvanligt | Mindre end sædvanligt | Meget mindre end sædvanligt |
| 9. Følt dig ulykkelig og nedtrykt? | Nej slet ikke | Ikke mere end sædvanligt | Noget mere end sædvanligt | Meget mere end sædvanligt |
| 10. Følt nedsat selvtillid? | Nej slet ikke | Ikke mere end sædvanligt | Noget mere end sædvanligt | Meget mere end sædvanligt |
| 11. Syntes at du ikke er noget værd? | Nej slet ikke | Ikke mere end sædvanligt | Noget mere end sædvanligt | Meget mere end sædvanligt |
| 12. Følt dig rimelig lykkelig alt taget i betragtning? | Mere end sædvanligt | Omtrent det samme som sædvanligt | Mindre end sædvanligt | Meget mindre end sædvanligt |

# Appendix C: CONSORT items which will be followed in the presentation of results and discussion in publications of the trial:

| CONSORT – Statement (CON) | Non-Pharmacological Treatment Interventions (NPT) |
|---|---|
| **Results – participant flow (download diagram)** | |
| **13a** For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome.<br>13b For each group, losses and exclusions after randomization, together with reasons. | The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider or in each center. |
| **Implementation of intervention** | |
| | Details of the experimental treatment and comparator as they were implemented. |

| CONSORT – Statement (CON) | Non-Pharmacological Treatment Interventions (NPT) |
|---|---|
| **Results – Recruitment** | |
| **14a** Dates defining the periods of recruitment and follow-up.<br>**14b** Why the trial ended or was stopped. | |

| CONSORT – Statement (CON) | Non-Pharmacological Treatment Interventions (NPT) |
|---|---|
| **Results – baseline data** | |
| **15** A table showing baseline demographic and clinical characteristics for each group | When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group. |

| CONSORT – Statement (CON) | Non-Pharmacological Treatment Interventions (NPT) |
|---|---|
| **Results – numbers analyzed** | |
| **16** For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups. | |

| CONSORT – Statement (CON) | Non-Pharmacological Treatment Interventions (NPT) |
|---|---|
| **Results – Outcomes and estimation** | |
| **17a** For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval).<br>**17b** For binary outcomes, presentation of both absolute and relative effect sizes is recommended. | |

| CONSORT – Statement (CON) | Non-Pharmacological Treatment Interventions (NPT) |
|---|---|
| **Results – ancillary analyses** | |
| **18** Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory. | |

| CONSORT – Statement (CON) | Non-Pharmacological Treatment Interventions (NPT) |
|---|---|
| **Results – Harms** | |
| **19** All important harms or unintended effects in each group (for specific guidance see CONSORT for harms). | |

| CONSORT – Statement (CON) | Non-Pharmacological Treatment Interventions (NPT) |
|---|---|

| **Discussion – limitations** | |
|---|---|
| **20** Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses. | |

| **CONSORT – Statement (CON)** | **Non-Pharmacological Treatment Interventions (NPT)** |
|---|---|
| **Discussion – generalizability** | |
| **21** Generalizability (external validity, applicability) of the trial findings. | Generalizability (external validity) of the trial findings according to the intervention, comparators, patients, and care providers and centers involved in the trial. |

| **CONSORT – Statement (CON)** | **Non-Pharmacological Treatment Interventions (NPT)** |
|---|---|
| **Discussion – Interpretation** | |
| **22** Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence. | **20** In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group. |

| **CONSORT – Statement (CON)** | **Non-Pharmacological Treatment Interventions (NPT)** |
|---|---|
| **Other information - registration** | |
| **23** Registration number and name of trial registry. | |