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

Research Protocol

May 2013

Poul Lundgaard Bak, Carsten Obel, Jin Liang Zhu

CONSORT – Statement (CON)	Non-Pharmacological Treatment Interventions (NPT)	Cluster Trials (CT)	Pragmatic Trials (PT)
Title and abstract			
1a Identification as a randomized trial in the title. **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.	Identification as a cluster randomized trial in the title.	

Resilience in youth education - a pragmatic trial of a Brief Intervention Program.

Content

Background

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

CONSORT – Statement (CON)	Non-Pharmacological Treatment Interventions (NPT)	Cluster Trials (CT)	Pragmatic Trials (PT)
Introduction - Background and objectives			
2a Scientific background and explanation of rationale. **2b** Specific objectives or hypotheses.		**2a** Rationale for using a cluster design. **2b** Whether objectives pertain to the cluster level, the individual participant level or both.	Describe the health or health service problem that the intervention is intended to address and other interventions that may commonly be aimed at this problem.

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.

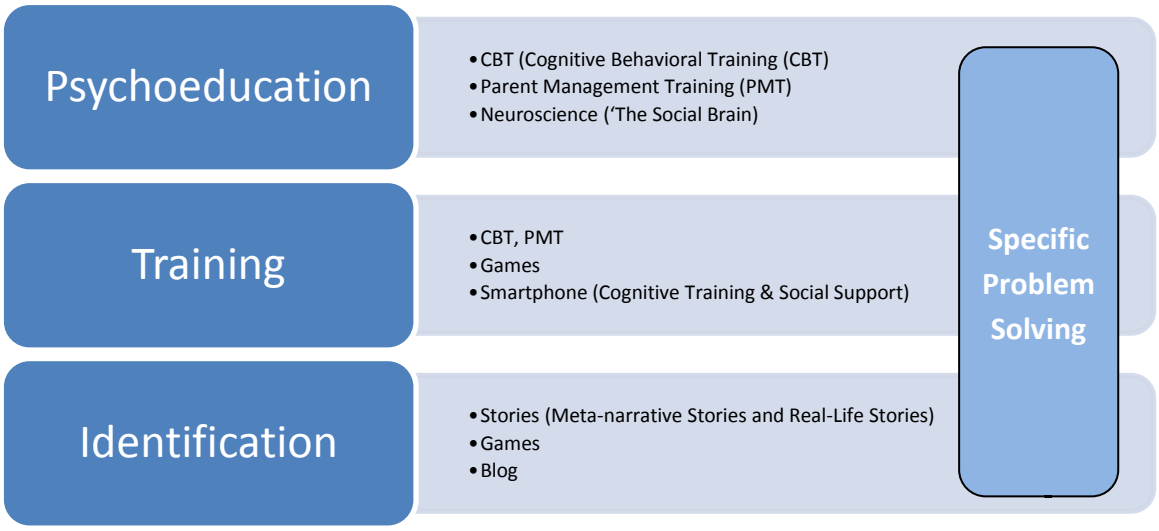
The intervention program is designed to respond to calls to exploit low cost & large scale intervention delivery models expressed by for instance Professor Allan Kadzin (Kadzin & Blasé 2011) and Professors Anthony Roth and Peter Fonagy (Roth and Fonagy 2006). The idea is to meet the socio-economic pressure 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 (Oʾ 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[1]) 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 can be used directly for children down to the age 6-7 and for younger children by the reinforcement of good parenting inherent in the program. 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 Robusthed.dk website (on the English sub-site "About Us" and on the website of the Child Health Mental Research Program here).

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 and families and 3000 parents) has demonstrated wide applicability and a high feasibility (Lundgaard Bak 2012).

[1] The English version webadress is myresilience.org

The program can be tested by logging in on www.Robusthed.dk (The program is in Danish and in English):

User name: rpres Password: rpres

In the intervention program all adults around the child are offered exactly the same background knowledge and practical knowledge of how resilience training of children and adolescents can be integrated in daily life. The purpose is to support the development of common knowledge and understanding about child development and provide opportunities to train coping situations with the child both at home and daycare /school. **The knowledge and tools of the program is communicated to the children and adolescents by 'their own adults'.** The program is designed to fit into ordinary curricular and extracurricular activities and contacts between families and professionals on group and/or individual level in order to minimize the need for extra resource input. The program is introduced for the target groups in standardized short lectures and courses and participants are given a trial-specific log-in to the program website.

The trials in the research project 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.*

3 large scaled trials are started in 2013-14 – covering children and adolescents in care (0-18 year), school projects (6-17 year) and youth education (15-25 year). This protocol concerns the youth education 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
DK interventions covered by future Danish applications				
Robusthed.dk	Stress	Young mothers		
			ADHD	
International interventions covered by international applications				
Robusthed.dk			Greenland: Suicide prevention (the project starts Summer 2013)	
			EU-Harvard/USA mental disorder	

The Youth Education Trial

A worrying number of young people in Denmark do not get adequate education and training and the society has taken initiatives on several levels to help solve this challenge (The Ministry of Education 2012). The 53 Danish municipalities Youth Education Centers (YEC) have a key role in this work. The YEC's are education advisory centers and have contact with every young person aged 15-25, that is about 680.000 persons. This includes monitoring of their academic performance and educational carrier and personal advice and guidance for those who need it.

There can be many reasons why a young person never start or drop out of an education. For a significant proportion it is about vulnerability / lack of resilience in one form or another. That is why it is relevant to investigate whether a Robusthed.dk program intervention through YEC's *and* Youth Education Institutions (YEI) can have any measurable effects on drop-out rates among vulnerable students.

Trial design & intervention

CONSORT – Statement (CON)	Non-Pharmacological Treatment Interventions (NPT)	Cluster Trials (CT)	Pragmatic Trials (PT)
Methods – Trial Design			
3a Description of trial design (such as parallel, factorial) including allocation ratio. **3b** Important changes to methods after trial commencement (such as eligibility criteria), with reasons.		**3a** Definition of cluster and description of how the design features apply to the clusters.	

CONSORT – Statement (CON)	Non-Pharmacological Treatment Interventions (NPT)	Cluster Trials (CT)	Pragmatic Trials (PT)
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. **4a** Description of the different components of the interventions and, when applicable, descriptions of the procedure for tailoring the interventions to individual participants. **4b** Details of how the interventions were standardized. **4c** Details of how adherence of care providers with the protocol was assessed or enhanced.	**5** Whether interventions pertain to the cluster level, the individual participant level or both.	Describe extra resources added to (or resources removed from) usual settings in order to implement intervention. Indicate if efforts were made to standardize the intervention or if the intervention and its delivery were allowed to vary between participants, practitioners, or study sites. Describe the comparator in similar detail to the intervention.

This is a pragmatic trial. No methods will be changed after trial commencement.

The trial is developed and implemented in dialogue with the Danish Youth Education Developmental Center (www.UUDanmark.dk).

The trial is focused on the YEC's and two YEI types in which the proportion of vulnerable students and dropout rates is relatively high (DCUM 2009):

1. SOSU schools (SOSU = Social & Health Helper and Assistants).
2. Technical Schools (craftsmen educations).

The total number of EYC's and YEI schools in the country is rather small which makes it difficult to run a cluster randomized trial. For that reason the selection of schools for intervention is pragmatic based on geographical distribution criteria reflecting the urban and rural regions of the country which is known to affect sociodemographic and cultural differences in the population.

There are 53 YEC's in Denmark of which 6 are selected for the intervention.
There are 16 SOSU schools in Denmark of which 5 are selected for the intervention.
There are 29 Technical Schools of which 10 are selected for intervention.

In participating centers and institutions all leaders and employees are offered a free standardized 3 hour introduction lecture and access to Robusthed.dk. In the introduction there will be a focus on how YEI teachers and consultants can use Robusthed.dk as a professional tool in line with other relevant tools. The YEI professionals are given an institution-specific Robusthed.dk password, which they can share with all

relevant persons in their target population (the vulnerable young people they meet, mentors, parents, teachers, etc.).

There will be no project costs for the participating centers and institutions apart from prioritizing time for the 3 hour introduction

The intervention pertains both to the cluster level and individual participant level.

Participant eligibility

CONSORT – Statement (CON)	Non-Pharmacological Treatment Interventions (NPT)	Cluster Trials (CT)	Pragmatic Trials (PT)
Methods - Participants			
4a Eligibility criteria for participants. 4b Settings and locations where the data were collected.	**3** When applicable, eligibility criteria for centers and those performing the interventions.	**4a** Eligibility criteria for clusters.	**3** Eligibility criteria should be explicitly framed to show the degree to which they include typical participants and/or, where applicable, typical providers (eg, nurses), institutions (eg, hospitals), communities (or localities eg, towns) and settings of care (eg, different healthcare financing systems).

All YEC's, SOSU and Technical schools in Denmark are included in the pool from which control and intervention groups of schools are selected. Thus all are eligible and no one is excluded.

Outcome measures

CONSORT – Statement (CON)	Non-Pharmacological Treatment Interventions (NPT)	Cluster Trials (CT)	Pragmatic Trials (PT)
Methods - Outcomes			
6a Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed. **6b** Any changes to trial outcomes after the trial commenced, with reasons.		**6a** Whether outcome measures pertain to the cluster level, the individual participant level or both.	Explain why the chosen outcomes and, when relevant, the length of follow-up are considered important to those who will use the results of the trial.

Outcome will be judged by YEI standard data on young people's education which are already systematically collected in a nationwide database (UNI-C). Thus it will not be necessary to collect extra data in the project. Drop-out rates will be primary outcome measure. Data from the participating centers and schools will be compared to data from all the other centers and schools in Denmark. Datasets before and after intervention will be included. Impact will be assessed at 1 and 3 years after the intervention. Because YEC and YEI data are CPR-based, one can in principle make follow-ups after an arbitrary number of years on register data.

The outcome measure pertains both to the cluster level and individual participant level.

Sample size calculation

CONSORT – Statement (CON)	Non-Pharmacological Treatment Interventions (NPT)	Cluster Trials (CT)	Pragmatic Trials (PT)
Methods – Sample Size			
7a How sample size was determined. **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.	**7a** Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intra-cluster correlation (ICC or *k*), and an indication of its uncertainty.	If calculated using the smallest difference considered important by the target decision maker audience (the minimally important difference) then report where this difference was obtained.

The intervention group has been selected on pragmatic reasons as described in the trial design and intervention section above. For that reason a sample size calculation is not relevant.

Randomization and blinding

CONSORT – Statement (CON)	Non-Pharmacological Treatment Interventions (NPT)	Cluster Trials (CT)	Pragmatic Trials (PT)
Methods – Randomization – sequence generation			
8a Method used to generate the random allocation sequence. **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.	**8b** Details of stratification or matching if used.	
CONSORT – Statement (CON)	**Non-Pharmacological Treatment Interventions (NPT)**	**Cluster Trials (CT)**	**Pragmatic Trials (PT)**
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.		Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both.	
CONSORT – Statement (CON)	**Non-Pharmacological Treatment Interventions (NPT)**	**Cluster Trials (CT)**	**Pragmatic Trials (PT)**
Methods – Randomization - implementation			
10 Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions?		Replace by 10a, 10b and 10c. **10a** Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions. **10b** Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling). **10c** From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomization.	
CONSORT – Statement (CON)	**Non-Pharmacological Treatment Interventions (NPT)**	**Cluster Trials (CT)**	**Pragmatic Trials (PT)**
Methods - Blinding			
11a If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how. **11b** If relevant, description of the similarity of interventions.	**11a** Whether or not those administering co-interventions were blinded to group assignment. **11b** If blinded, method of blinding and description of the similarity of interventions.		If blinding was not done, or was not possible, explain why.

As described above this is not a randomized trial.

Statistical Methods

CONSORT – Statement (CON)	Non-Pharmacological Treatment Interventions (NPT)	Cluster Trials (CT)	Pragmatic Trials (PT)
Methods - Statistical methods			
12a Statistical methods used to compare groups for primary and secondary outcomes. **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.	**12a** How clustering was taken into account.	

Logistic regression models will be used to estimate the impact of the intervention on the binary primary outcome variable (dropout rate).

Separate analyses will be done for the EYC's and the two YEI types.

Time table

2013		2014	2015	2016	2017	2018
Prepare trial	intervention		Data collection & analyses			Publication & knowledge dissemination

Ethical and legal consideration

According to Danish Ethical legislation (§ 2 no. 1, law no 593, June 14th, 2011) this trial does not need ethical committee approval.

Applications for trial approval have been send in June 2013 to The Danish Data Protection Agency and the Danish Ministry of Children and Education.

This trial follows the CONSORT – statement criteria for Pragmatic Trials.

The control group is a "shadow control group" – because the control group schools do not know they are included as control in a scientific trial and because outcome exclusively relies on standard register data collected anyway. The control group continues "Service/Treatment As Usual". Being in the control group does not restrict their actions or services in any way. Thus the control group schools are not 'disturbed' in anyway.

The intervention Robusthed.dk consists of the dissemination of scientifically based knowledge and inspiration for reflection and conversations in the daily setting of family and institutional life. The specific use of the elements in the program is tailored by the responsible adults around the children. No children in the intervention or control groups are prevented from receiving any kind of service as usual as a result of the trials.

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 www.iupgrowth.com .

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 A.

Scientific Perspectives

We believe that the intervention project will contribute with knowledge about whether it is possible to support young people 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 key organizations**.**

On a national level it is estimated that 1-2 consultants per municipality can implement the program adequately in a community wide setting (youth education and public school settings as well as other relevant 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.

If the results of the research project show that giving log-in to the program website is “enough” – that is introductory lectures and courses are not necessary, implementation costs are drastically reduced.

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

Protocol access

CONSORT – Statement (CON)	Non-Pharmacological Treatment Interventions (NPT)	Cluster Trials (CT)	Pragmatic Trials (PT)
Other information - protocol			
24 Where the full trial protocol can be accessed, if available.			

The full trial protocol will be available (when completed) at The Child Mental Health Research Program website www.iupgrowth.com .

Funding

CONSORT – Statement (CON)	Non-Pharmacological Treatment Interventions (NPT)	Cluster Trials (CT)	Pragmatic Trials (PT)
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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How Low-Cost Randomized Controlled Trials Are Possible in Many Areas of Social Policy:
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The Government Office for Science, London: Foresight Mental Capital and Wellbeing Project. 2008.

Appendix A: 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)	Cluster Trials (CT)	Pragmatic Trials (PT)
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. 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.	**13a** For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analyzed for the primary outcome. **13b** For each group, losses and exclusions for both clusters and individual cluster members.	The number of participants or units approached to take part in the trial, the number which was eligible, and reasons for non-participation should be reported.
Implementation of intervention			
	Details of the experimental treatment and comparator as they were implemented.		

CONSORT – Statement (CON)	Non-Pharmacological Treatment Interventions (NPT)	Cluster Trials (CT)	Pragmatic Trials (PT)
Results – Recruitment			
14a Dates defining the periods of recruitment and follow-up. **14b** Why the trial ended or was stopped.			

CONSORT – Statement (CON)	Non-Pharmacological Treatment Interventions (NPT)	Cluster Trials (CT)	Pragmatic Trials (PT)
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.	Baseline characteristics for the individual and cluster levels as applicable for each group.	

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

CONSORT – Statement (CON)	Non-Pharmacological Treatment Interventions (NPT)	Cluster Trials (CT)	Pragmatic Trials (PT)
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). **17b** For binary outcomes, presentation of both absolute and relative effect sizes is recommended.		**17a** Results at the individual or cluster level as applicable and a coefficient of intra-cluster correlation (ICC or k) for each primary outcome.	

CONSORT – Statement (CON)	Non-Pharmacological Treatment Interventions (NPT)	Cluster Trials (CT)	Pragmatic Trials (PT)
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)	Cluster Trials (CT)	Pragmatic Trials (PT)
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)	Cluster Trials (CT)	Pragmatic Trials (PT)
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)	Cluster Trials (CT)	Pragmatic Trials (PT)
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.	Generalizability to clusters and/or individual participants (as relevant).	Describe key aspects of the setting which determined the trial results. Discuss possible differences in other settings where clinical traditions, health service organization, staffing, or resources may vary from those of the trial.

CONSORT – Statement (CON)	Non-Pharmacological Treatment Interventions (NPT)	Cluster Trials (CT)	Pragmatic Trials (PT)
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)	Cluster Trials (CT)	Pragmatic Trials (PT)
Other information - registration			
23 Registration number and name of trial registry.			