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

August 2014

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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 for children and young people in foster care and residential care – a survey and a pragmatic cluster randomized trial of a Brief Intervention Program.

Content

Dansk Resume

Børn og unge, som er anbragt uden for eget hjem, hos plejefamilie eller på opholdssted / døgninstitution, er i en udsat livssituation med forøget risiko for fysiske og psykiske helbredsproblemer og sociale problemer senere i livet. Plejeforældre og professionelle på opholdssteder og døgninstitutioner har en vigtig og også udfordrende opgave. Det er en stor gave at få kvalificeret hjælp af professionelle og en stor gave at kunne hjælpe – selvom det ikke altid er nemt – og det lykkes heller ikke altid. Oplevelse af nederlag og stress er desværre ikke ukendt og risikoen for sammenbrud i et plejeforhold er ikke ubetydelig**.** Anbringelser er også en kostbar social foranstaltning - som er under debat på grund af den samfundsøkonomiske situation.

I nærværende projekt inviteres alle anbragte børn og unge i Danmark (cirka 12.500) og plejeforældre og ansatte på opholdssteder og døgninstitutioner til at medvirke i en spørgeskemaundersøgelse hvor de får mulighed for at fortælle lidt om, hvordan de har det. I undersøgelsen får børn og unge får selv mulighed for at give deres mening til kende. De voksne svarer på spørgsmål om deres oplevelse af barnets situation, og de voksne besvarer spørgsmål om deres egen oplevelse af trivsel og stress i forbindelse med arbejdet. På opholdssteder og døgninstitutioner undersøges, hvor hyppigt det er nødvendigt at fastholde børn/unge for at de ikke skader sig selv eller andre. En lille gruppe (tilfældig stikprøve) plejemødre inviteres desuden til at medvirke i en udvidet stressundersøgelse med måling af stress-hormonet kortisol i en lille hårprøve. Mængden af hårkortisol er et mål for det samlede stressniveau i de foregående måneder.

Formålet med undersøgelsen er at bidrage med viden, som forhåbentlig kan være med til at forbedre hverdagen for børn og unge og plejeforældre og ansatte på opholdssteder og døgninstitutioner.

I forbindelse med spørgeskemaundersøgelsen tilbydes 2/3 af alle anbringelsessteder (med i alt cirka 8.000 anbragte børn og unge) (cluster-randomiseret stikprøve) adgang til et nyt videns- og inspirationsprogram om robusthed for børn, unge og voksne (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 fastholdelse af børn og unge reduceret med mere end 90 %.

1 år senere inviteres alle deltagere til igen at besvare de samme spørgsmål (+ ny Hårkortisol prøve i gruppen af plejemødre). 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 hyppigheden af sammenbrud i plejeforhold samt læringsresultater (skolebørn).

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.

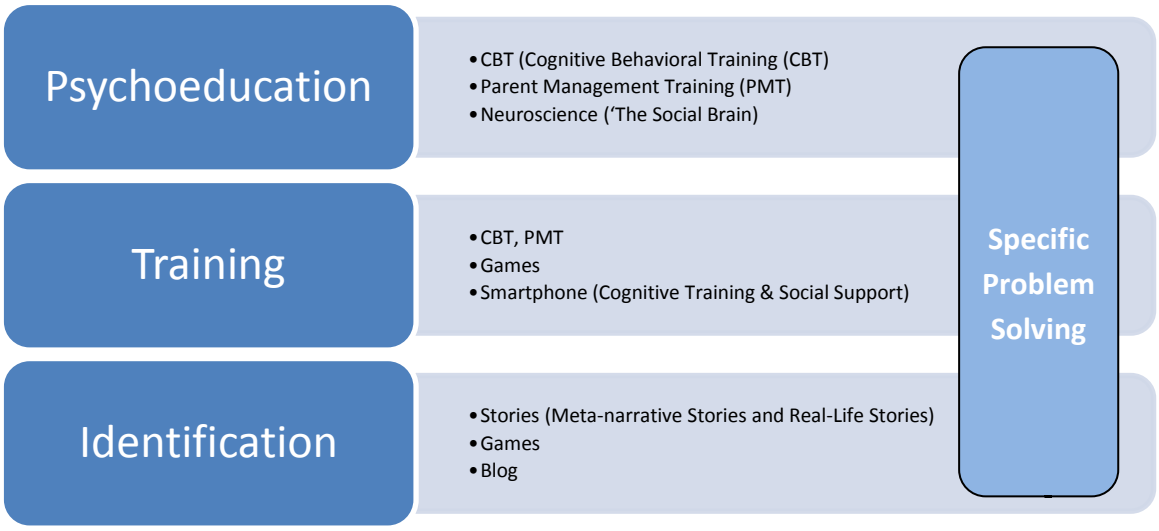
The intervention program is designed to respond to calls to exploit low cost & large scale intervention delivery models expressed by for instance Professor Allan Kadzin (Kadzin & Blasé 2011) and Professors Anthony Roth and Peter Fonagy (Roth and Fonagy 2006). The idea is to meet the socio-economic pressure 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 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 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 Children in Care 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				
			Greenland: Suicide prevention (the project starts Summer 2013)	
Robusthed.dk			EU mental disorder	

The Care Trial

The Care Trial is developed and implemented in dialogue with the Social Manager Association of the municipalities in Denmark (Socialchef-foreningen), Local Government Denmark (LGDK = Kommunernes Landsforening), the Danish Foster Care Family Association and the two Danish associations for Residential Care Institutions.

Children and young people taken into foster care and residential care are – for many reasons - in a vulnerable position in life (that's why they are taken into care). Their health risks and social risks in life are increased. This has been documented by the Danish National Centre for Social Research and many others. In a significant number of cases the care decision and placement is unstable which contributes to the vulnerability of the children and adolescents. In nearly half of all cases where adolescents are taken into care, their place of care is changed one or more times - for complex reasons, but often emotional vulnerability and social marginalization is involved as well as systemic factors in the municipality organizations (Egelund et al 2010). The collapse rate is in the same order of magnitude in comparable countries.

The number of children and young people taken into care in Denmark and reasons for care decisions are collected by Ankestyrelsen and published yearly (Ankestyrelsen 2010). Approximately 12.500 children and young people are in care in a given year. Each year approximately 3000 new care decisions are made.

In general the incidence of care is rising with age:

Age group	Care incidence 2010
0-3 year	1.4 / 1000
15-17 year	5,56 / 1000

In the period 2007-2010 the incidence has been decreasing in all age groups except for the 0-3 year age group. The reasons for these changes are largely unknown.

Children and young people taken into care are considered as an important welfare challenge and the political and the media focus on this group is high. Systematic data collection on the health and wellbeing of children taken into care for planning, method development, evaluation and research is yet very limited which makes decision making difficult.

Unfortunately no high quality intervention research exists in the field either. A 2009 Cochrane review concluded that although training programs have proliferated, there has been minimal evaluative research to determine whether they are effective (Turner 2009). This conclusion is supported by other reviewers as well (Leve et al 2012).

The current project is designed to meet both the data challenge and the intervention challenge**.** The data collected for evaluating the efficiency of the intervention will also give highly valuable general knowledge about the welfare of children and adolescents in care because the project is nationwide and involves all children and adolescents in care.

This project is also the first step in building up a surveillance system for monitoring the welfare of children and adolescents in care in the future as an aid to case handling, local planning and intervention evaluation as well as research. More about this surveillance project on the Child Mental Health Research Program Website www.iupgrowth.com.

Recently there has been public concern in Denmark about the stress level among foster care parents and professionals in residential institutions and how that may affect the wellbeing and health of the children and adolescents in care. This concern is connected to the fairly large structural changes in the care sector which currently is implemented by politicians and managers. There is no data-based knowledge about the actual stress level right now. For that reason an adult work stress survey is included in this study and a Hair Cortisol study (see below).

Results from a recent interview study among 113 Danish children and young people (Børnerådet 2012) have indicated a high frequency of staff using force in residential institutions with the aim of protecting children and adolescents from harming themselves and others.
A pilot study using elements of Robusthed.dk in a club with 140 adolescents from a low income area is relevant in this context. The experience was that the intervention helped to reduce the level of disruptive behavior and conflicts significantly. The registered level of incidents of using force to prevent physical fights and damage was reduced from 150 incidents per year to less than 10 per year. An important factor is probably that the program has an impact on the stress-level on the kids as well as the adults (Lundgaard Bak 2012). It will be interesting to see if Robusthed.dk may help to reduce the frequency of using force in residential institutions as well. This will be monitored in the project.

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.

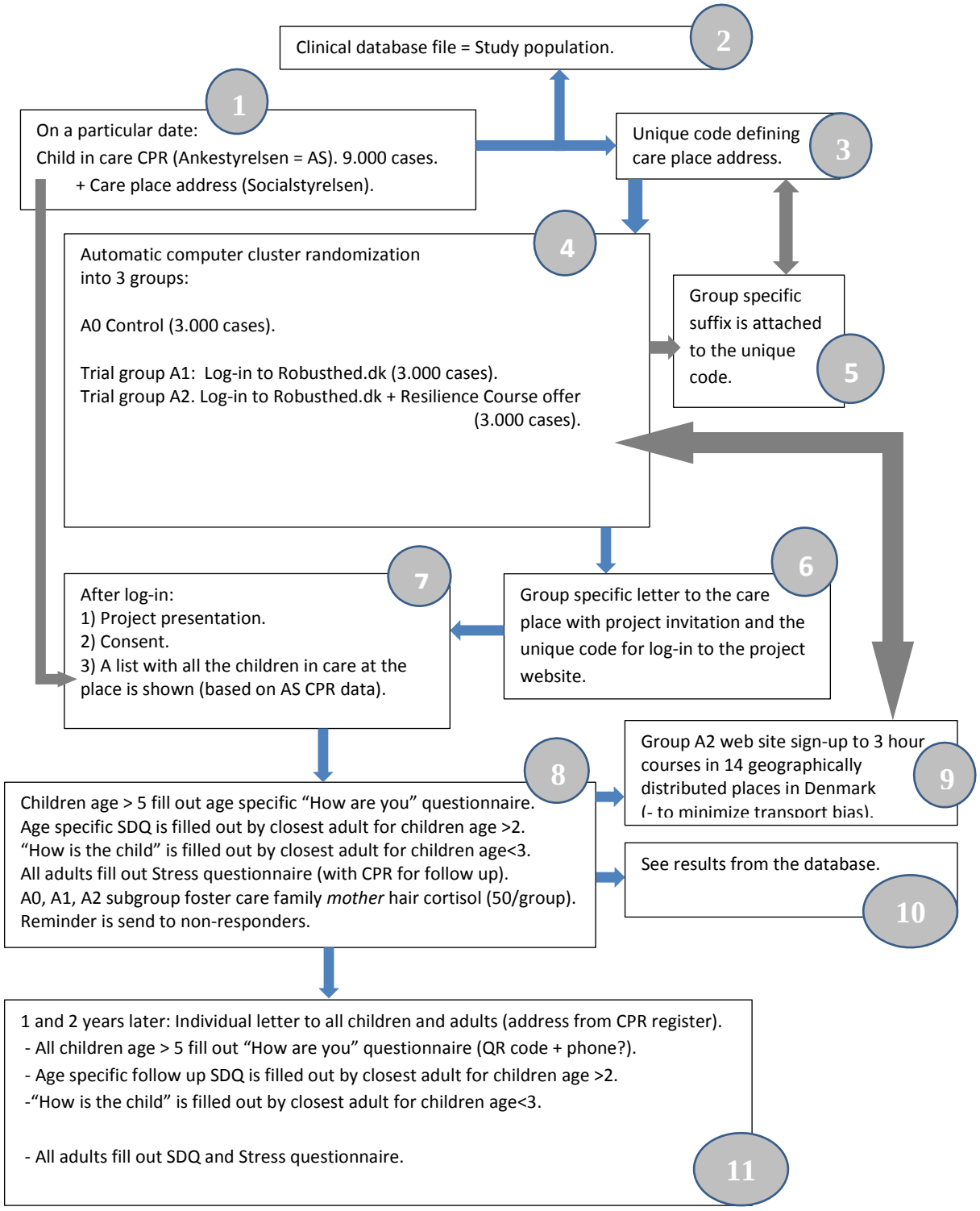
This is a pragmatic cluster randomized trial. No methods (such as eligibility criteria) will be changed after trial commencement.

The study population is defined in cooperation with Ankestyrelsen who keeps records on all children and adolescents in care and Socialstyrelsen who keeps records on all foster care families and residential institutions in Denmark. On a particular day a unique code is attached to every child record identifying the care place. This constitutes the study population (a cohort with about 9.000 individuals). The identification data are combined in a file which is placed in Statistic Denmark (for safety reasons).

All children in one foster care family or in the same residential institution are defined as a cluster. Hitherto experiences with the Resilience Program clearly indicate that professionals of whatever background integrate the knowledge and tools of the program in their daily practice once they have been introduced. For that reason it will not be possible to prevent contamination by preference of child or professional if randomization on individual level within a foster care family or residential institution is chosen (selection bias). Therefore cluster randomization is chosen.

Trial design and data flow is shown in the following diagram.

Diagram 1: Trial design and dataflow.



Comments:

1 2 3 The Study population is defined in cooperation with Ankestyrelsen who keeps records on all children and adolescents in care and Socialstyrelsen who keeps records on all foster care families and residential institutions in Denmark. On a particular day a unique code is attached to every child record identifying the care place. This constitutes the study population (a cohort with about 9.000 individuals). The identification data are combined in a file which is placed in secure clinical database/server (for safety reasons).

4 The study population in the data file is cluster randomized by a computer randomization program. All children in one foster care family are defined as a cluster and all children living in the same residential institution is defined as a cluster. This is to ensure that participants in trial and control groups do not live in the same family/institution.

The study population is randomized into 3 groups:

- **Group A0** is the control group (3.000 participants). The participants in the control group (comparator) receive "Services/Treatment As Usual (TAU)". As far as we know this is highly variable – depending on the age of the child, the characteristics of their problems and the characteristics of the care place. There are potentially a large number of confounding factors and that is one of the reasons for designing this large scale randomized trial.

- **Group A1** is one of the two trial groups (3.000 participants). Participants allocated to this group will be offered a log-in to Robusthed.dk.

- **Group A2** is the other of the two trial groups (3.000 participants). Participants allocated to this group will be offered a log-in to Robusthed.dk and a free 3 hour Resilience Course.

The two trial groups A1 and A2 will thus be subject to two different models of low cost delivery of the Robusthed.dk program. This design allows investigation of the eventual difference in impact with two different low cost models of delivery (Kadzin & Blasé 2011).

5 A control/trial group specific suffix is automatically added to the identification code in the data file for future record identification and data analysis.

6 Based on the address list in the identification file and the allocation, group-specific letters are send to foster care families and residential institutions with an invitation to join the project including a unique log-in code to a project website. The project is shortly described in the letter together with group specific information ((See Appendix A).

7 After log-in the project is presented in more details with a consent form (See Appendix B). After consent, a name list of all the children in care is shown. This list is automatically generated based on identification file data.

8

Participants fill out questionnaires on the website (se Appendix C)

- All children age >5 fill out a 14 item "How are you" questionnaire. Small children will be aided by "animated questionnaire". This questionnaire has been tailored to this trial based on a number of very simple daily language questions used often and for many years in a range of different widely used public health contexts. The questionnaire is pilot tested on the web platform to be used. Each answer is scored 0, 1 or 2 (positive) points. Max positive "well-being" score is thus 28.
- Age specific SDQ for each child age >2 is filled out by closest adult. SDQ (Strength and Difficulty Questionnaire) is a simple internationally validated questionnaire. See http://sdqinfo.org/ . SDQ is also scores in accordance with the standard procedure for this questionnaire.
- For children age <3 the closest adult fill out a 1o item questionnaire "How is the child". This questionnaire has also been tailored to this trial based on a number of very simple daily and broadly recognized observations of small children's wellbeing and behavior. The questionnaire is pilot tested on the web platform to be used. Each answer is scored 0, 1 or 2 (positive) points. Max positive score is thus 20.
- All adults fill out a 15 item work stress questionnaire (with CPR, mail & phone for follow up) which is scored in two dimensions (work satisfaction and stress level).

A reminder will be send to non-responders.

9

On the website Group A2 participants can sign-up for the 3 hour standard Resilience courses which will be held in 8-10 geographically distributed places in Denmark in order to minimize transport bias.

10

When the first questionnaire has been answered, participants will get access on the website to result distributions from the database. It is expected that this will be a motivation for answering all questionnaires – because one can compare own results with the part of the study population which has hitherto answered the questions.

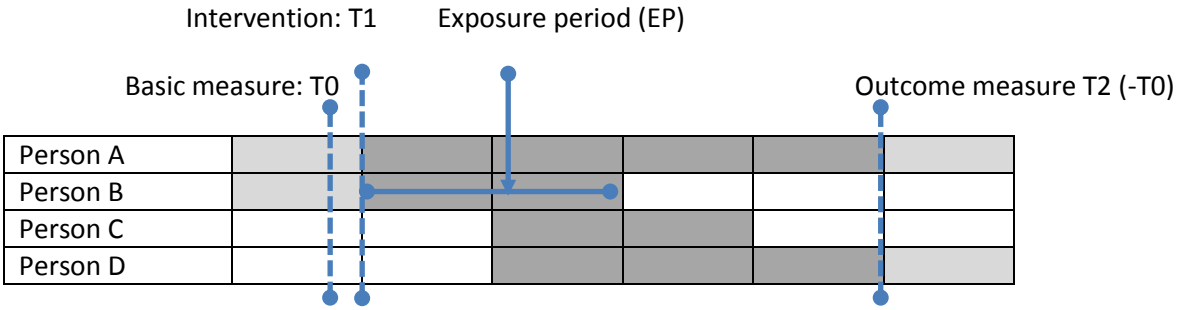
11

1 and 2 years later, individual letters with new unique log-in codes are send to all children and adults in the study population based on updated addresses from the CPR register – with invitation to log-in and answer the same questionnaires as when the project started a year earlier. The information in the letters and on the website will in principle be the same as seen in appendix A and B – updated to this context. This procedure is considered necessary because a substantial proportion of the study population – especially among the children, has moved to other places within the follow up period. After log-in participants answer the same questionnaires as before intervention (see A8 above). Participants will again get access to result distributions from the database and moreover they can compare their personal results a year ago with current results.

Exposure note

In care families/institutions there is a substantial flow of children who moves in and out (The prevalence of children in care is around 9.000, and the number of new care decisions is around 3000 pr. year. This flow will influence for how long time a child eventually will be living in a care setting in which the Resilience Program has been implemented – that is the Resilience Program "Exposure time-period". In principle there are 4 different exposure time patterns:

Person present in family/institution ***outside*** the project period.	
Person present in family/institution ***inside*** the project period.	



The study population is defined at time T0. The time between T0 and T1 should be as short as possible. A and B types will be included in T2 follow up data collection and analyses.

It may be possible to test the hypothesis that the Resilience Program has "dose-response" effects by correlating the exposure time length in type B individuals with effect sizes.

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 children and adolescents taken into in care in Denmark and all care placements are included in the study. Thus no one is excluded and all are eligible.

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

- Questionnaire data from children, adolescents and the adult professionals before and 1 year after intervention.
- Register data. Because the CPR number of all children and adolescents in the study population is stored in a data file in Statistics Denmark, data on every participant can be identified in relevant other registers (legal and ethical considerations - see below).

All outcome measures pertain to the individual participant level. No trial outcome measures will be changed after trial commencement. The duration of a care period varies a lot (the prevalence of children in care is about 9.000 and the incidence of care decisions is 3.000 pr. year). For that reason – and in negotiations with the partner organizations, a follow up period of 2 year is found to be appropriate.

Primary outcome measures:

A. Child Academic performance (register data).
B. Care collapse frequency (register data).

Secondary outcome measures:

C. Change in Child “How are you” questionnaire score from baseline to follow up (children age > 5).
D. Change in SDQ score from baseline to follow up (children age > 5).
E. Change in “How is the child” score from baseline to follow up (children age 2-6).
F. Change in Adult Stress Score from baseline to follow up.
G. School absenteeism.

Outcomes A and C-G are continuous variables, while outcome B is binary. We expect outcomes A and C-H to be normal distributed, or approximately after transformation (Z-score or log-transformation). The means and the standard deviations for outcomes A and C-H will be presented for each intervention arm, as well as the care collapse rate. The effect estimates of intervention will be calculated by comparing intervention groups 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.
The age distribution of children and adolescents is different in foster care families and residential institutions (younger children are more frequently placed in foster care families). Therefore separate analyses for foster care families and residential institutions will also be conducted.

Sample size calculations

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.

For academic performance

We use subject "Danish Reading" as an example. The mean score of Danish Reading among children in care is estimated about 4.2 with standard deviation 0.4 (Data from the Databank in the Ministry of Education). From a societal perspective we estimate that a 10% increase in the mean score after the trial would be considered to be sufficiently interesting for decision makers to eventually implement the program on a larger scale. If we choose significance level of 0.05 and power of 80%, we need 15 children in both trial group and control group. If we expect 5% increase in the mean score after the trial, we need 57 children in both trial group and control group. Thus in every case our sample size is well beyond the necessary level for this parameter.

For care collapse

The rate of care collapse among children in care is reported about 40%. From a societal perspective we estimate that a 10% reduction of this rate after the trial would be considered to be sufficiently interesting for decision makers to eventually implement the program on a larger scale. When we choose significance level of 0.05 and power of 80%, we need 2361 children in both trial group and control group.

We will do the trials separating by foster families and care institutions. There are 1 to 2 children in a foster family; if we assume intra-cluster correlation coefficient (ICC) of 0.02, we need 1590 families in each trial group.

We have 841 registered care institutions with at least one available place (range 1-300). Overall, mean=14.2 and SD=20.4. If we assume intra-cluster correlation coefficient (ICC) of 0.02, we need 199 care institutions in each trial group. Assuming that 80% of the available places are occupied, we need 248 care institutions in each trial group.

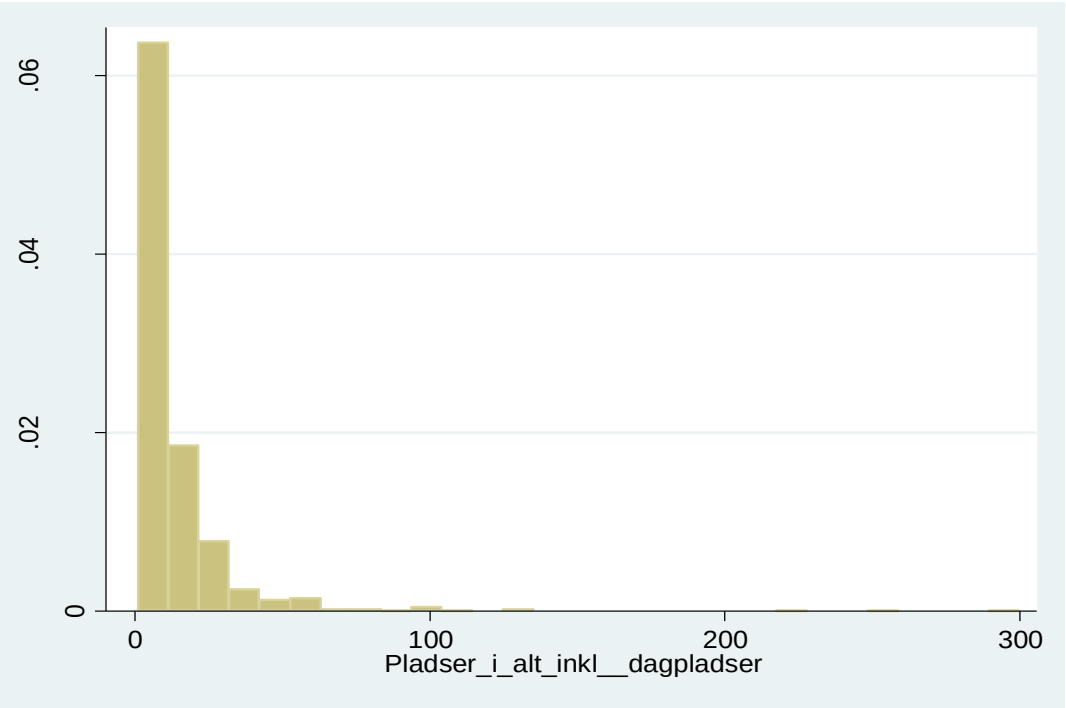


Figure. Distribution of care institution's size (available places).

For SDQ total score

The rate of abnormal SDQ total score among children in care is reported about 50% (SFI 2008). From a societal perspective we estimate that a 10% reduction of this rate after the trial would be considered to be sufficiently interesting for decision makers to eventually implement the program on a larger scale. If we choose significance level of 0.05 and power of 80%, we need 1605 children in each trial group and control group to detect 10% reduction in the rate of abnormal SDQ total score.

We will do the trials separating by foster families and care institutions. There are 1 to 2 children in a foster family; if we assume intra-cluster correlation coefficient (ICC) of 0.02, we need 1081 families in each trial group.

We have 841 registered care institutions with at least one available place (range 1-300). Overall, mean=14.2 and SD=20.4. If we assume intra-cluster correlation coefficient (ICC) of 0.02, we need 135 care institutions in each trial group. Assuming that 80% of the available places are occupied, we need 169 care institutions in each trial group.

Randomization

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.

Randomization and blinding procedures are described in the Trial design and Intervention section above under the headings

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.	

Linear and logistic regression models will respectively be used to estimate the impact of the interventions on continuous and binary variables of the primary or secondary outcomes. The analyses will take into consideration clustering and a few covariates available at baseline, including sex, age, and grade. Intention to treat analyses will be applied to the primary outcomes, as the registers have information on almost all school children. The number needed to treat (NNT) for care collapse will also be calculated, ie, the number of children in care that need to be intervened for one to benefit (no care collapse) compared with a control in the trial.

We will do sub-analyses, stratified on foster and residential care, boy and girls, and younger and older age groups, since we expect that the impact of interventions will vary by care setting, sex and age.

Time table

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

Ethical and legal consideration

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

- The Ethical Committee has responded that the trial does not need approval.

This trial follows the CONSORT – statement criteria including the extensions for Non-pharmacological Treatment Interventions, Cluster Randomized Trials and Pragmatic Trials.

Information to participants in the trial groups: See appendix A and B.

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 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.

Any foster care family and institution can at any time – at the cluster level and the individual level, 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. The key collaborative organizations have shown great interest in participating in the trial.

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 on 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 pertains 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 vulnerable children, young people and families 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 (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.

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.

Trial registration

The trial is registered in ClinicalTrial.gov: **Registration number XXX**

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

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 Danish Tryg Foundation.

References

Ankestyrelsen: Anbringelsesstatistik 2010.

Børnerådet 2012: ”DE PRØVER AT GØRE DET SÅ NORMALT SOM MULIGT” ET INDBLIK I 113 ANBRAGTE BØRN OG UNGES LIV.

Egelund T, Jakobsen TB, Hammen I, Olsson M, Høst A. Sammenbrud i anbringelser af unge. SFI – Det nationale forskningscenter for Velfærd 2010.

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

Leve LD, Harold GT, Chamberlain P, Landsverk JA, Fisher PA, Vostanis P. Practitioner Review: Children in foster care – vulnerabilities and evidence-based interventions that promote resilience processes. Journal of Child Psychology and Psychiatry 2012 Aug 6. doi: 10.1111/j.1469-7610.2012.02594.x. [Epub ahead of print].

Moffitt TE, Arseneault L, Belsky D, Dickson N, Hancox RJ, Harrington H, Shouts R, Poulton R, Roberts BW, Ross S, Sears MR, Thomson WM, Caspi A. A gradient of childhood self-control predicts health, wealth and public safety. PNAS 2011; 108(7): 2693–8.

Montgomery P, Bjornstad G, Dennis J. Media-based behavioral treatments for behavioral problems in children. Cochrane Database Syst Rev. 2006 Jan 25;(1):CD002206

NICE: Promoting children’s social and emotional wellbeing in primary education. NICE 2008.

NICE: Promoting young people’s social and emotional wellbeing in secondary education. NICE 2009.

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.

Ottosen MH, Andersen D, Nielsen LP, Lausten M, Stage S. Børn og Unge i Danmark. Velfærd og Trivsel. SFI 2010.

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

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

SFI – Det Nationale Forskningscenter for Velfærd: Anbragte børn i tal. 2008

The Coalition for Evidence Based Policy: http://coalition4evidence.org/wordpress/?page_id=468
How Low-Cost Randomized Controlled Trials Are Possible in Many Areas of Social Policy: http://coalition4evidence.org/wordpress/wp-content/uploads/Rigorous-Program-Evaluations-on-a-Budget-March-2012.pdf

The Government Office for Science, London: Foresight Mental Capital and Wellbeing Project. 2008.

Turner W, Macdonald G, Dennis JA. Behavioral and cognitive behavioral training interventions for assisting foster carers in the management of difficult behaviour. Cochrane Review 2009.

Appendix A: Letter sends to foster care parents and residential institutions (in Danish).

Invitation

Sendt til alle plejefamilier, opholdssteder og døgninstitutioner

Dette er en invitation til at medvirke i en undersøgelse, der handler om, hvordan anbragte børn og unge har det, og hvordan professionelle, som arbejder med anbragte børn og unge, har det.

Formålet med undersøgelsen er at bidrage med viden, som kan være med til at forbedre hverdagen for anbragte børn og unge, og plejeforældre og ansatte på opholdssteder og døgninstitutioner.

Undersøgelsen er enkel og foregår således:

- Log ind på **www.voksop.dk** med nøglen: **12345** og koden: **ABCDE**
  Koden er unik for anbringelsesstedet og opbevares fortroligt.
- På hjemmesiden findes information og spørgeskemaer. Alle svar behandles naturligvis strengt fortroligt.
- Spørgeskemaerne er korte og kan udfyldes på få minutter.
- Med tiden kan verden forandre sig. Om et år beder vi derfor alle – i et nyt brev – om at besvare de samme spørgsmål igen. Og dermed er undersøgelsen færdig.

Da nogle af børnene bliver bedt om at besvare et spørgeskema, bedes I, evt sammen med sagsbehandler, tage stilling til forældremyndighedshavers samtykke ud fra gældende retningslinjer. Børn, som eventuelt har deltaget i SFI's interviewundersøgelse i foråret 2014, behøver ikke besvare børneskemaet her.

Når undersøgelsen er færdig, vil resultaterne blive præsenteret på landsforeningernes hjemmesider.

Brevet til forsøgsgruppe 1 indeholder desuden følgende afsnit:

Samtidig vil vi gerne tilbyde jer et nyt videns-program om Robusthed
Robusthed handler om at blive god til at klare livets udfordringer - især når det er svært.

Du kan se programmet her: **www.robusthed.dk**. Her har vi samlet praktisk viden om robusthed for børn, unge og voksne. Blandt andet god gammel og ny viden om tanker, følelser og hjernen, viden om mobning, samt gode historier og små spil, lege og øvelser. Der er inspiration til løsning af problemer og mulighed for at træne med sin smartphone. Det hele kan både læses og lyttes. På forsiden er der også link til et kort intro-foredrag om Robusthed.

Og brevet til forsøgsgruppe 1 indeholder derudover også detteafsnit:

Vi vil også gerne tilbyde jer et Live-foredrag om Robusthed og om Robustheds-programmet. Her kan du se, hvornår vi holder live-foredrag tæt på dig: **www.Robusthed.dk/foredrag**
Det er gratis, og der er ingen tilmelding.

Når hele undersøgelsen er færdig, vil resultater og konklusioner blive præsenteret på landsforeningernes hjemmesider.

Venlig hilsen
Læge Poul Lundgaard Bak
Forskningsprogrammet for Mental Børnesundhed.

Aarhus Universitet og Region Midt.

Undersøgelsen er støttet af Trygfonden og tilrettelagt i dialog med Ankestyrelsen, Socialstyrelsen, Socialchef-foreningen, Plejefamiliernes Landsforening, Landsforeningen af Opholdssteder og Foreningen af Danske Døgninstitutioner. Undersøgelsen er godkendt af Etisk Komite, Datatilsynet og Kvalitetsstyrelsen.

Appendix B: Information on the project website and consent form (in Danish).

Velkommen til undersøgelsen "Hvordan har du det?" – hvor alle anbragte børn og unge i Danmark *og* plejeforældre og ansatte på opholdssteder og døgninstitutioner får mulighed for at fortælle lidt om, hvordan de har det.

Formålet med undersøgelsen er at bidrage med viden, som kan være med til at forbedre hverdagen for børn og unge og plejeforældre og ansatte på opholdssteder og døgninstitutioner.

I har fået en log-in kode, som er unik for anbringelsesstedet. Koden er dannet på grundlag af oplysninger fra Ankestyrelsen og Socialstyrelsen om, hvilke børn og unge, der er anbragt hvor. Koderne er gemt i en sikker database, hvor ingen – heller ikke forskerne – kan få adgang til person-identificerbare oplysninger. Denne procedure sikrer på samme tid følgende:

- Vi har kunnet sende jer invitation til at deltage i undersøgelsen på grundlag af jeres adresse, uden at vide på person-niveau, hvilke børn / unge, der er anbragt hos jer på den dato, hvor datafilen fra Ankestyrelsen og Socialstyrelsen er dannet (11.8.2014).
- I kan logge ind på denne lukkede hjemmeside, hvor alle oplysninger krypteres, og *alle* spørgeskema svar gemmes fortroligt.
- I kan på listen nedenfor se, hvilke børn og unge, der er anbragt hos jer – og dermed er inviteret til at deltage i undersøgelsen – uden at andre har adgang til disse oplysninger på personniveau.
- Forskerne kan samle resultaterne fra alle deltagere uden at kunne se oplysninger på enkeltpersoner.

Når Du klikker på navnelisten nedenfor, kommer du til en samtykke-erklæring, vejledning i udfyldelse af spørgeskema – og til selve spørgeskemaerne. Spørgsmålene præsenteres på skærmen ét af gangen og læses op – så man også kan være med, selv om man ikke kan læse.

- Børn >5 år udfylder selv et skema.
- Nærmeste voksen udfylder et skema for hvert barn.
- Alle voksne på stedet, som har kontakt med børn og unge, udfylder et stress spørgeskema.

Spørgeskemaerne kan ses her: LINK - men de kan først besvares efter klik på navnelisten og informeret samtykke. Skemaerne er forskellige for yngre og ældre børn. Computeren sikrer automatisk, at det rigtige skema knyttes til hvert enkelt barn.

KLIK:

- Barn A - navn
- Barn B – navn
- Barn X – navn
- Voksen (plejeforælder eller ansat på opholdssted/døgninstitution)

Når man klikker på <u>barnets navn</u> kommer følgende samtykkeerklæring frem på skærmen:

Nærmeste voksen, som har bemyndigelse til det, skal afgive samtykkeerklæring på barnets vegne:

Jeg (skriv:---NAVN---CPR---) erklærer herved at have fået tilstrækkelig information om undersøgelsen ”**Hvordan har du det**”, til på vegne af ---BARN NAVN--- at acceptere, at han/hun besvarer spørgeskemaet.

”ACCEPT”

Kun når NAVN og CPR er udfyldt og der klikkes på ACCEPT, kommer man videre til spørgeskemaerne.

Hvis barnet er > 5 år vises følgende to felter på skærmen:

Klik her	Klik her
Spørgeskema til barnet: ”Hvordan har du det?”. Barnet skal så vidt muligt sidde alene og besvare spørgsmålene! Spørgsmålene bliver vist og læst op ét af gangen, så også mindre børn kan finde ud af det alene.	Spørgeskema til nærmeste voksen: ”Hvordan har barnet det?”.

Hvis barnet er < 6 år vises kun dette felt på skærmen.

Af sikkerhedsmæssige årsager kan der ikke rettes i et skema, når det *er* sendt.

Når et spørgeskema er besvaret, kan man få vist det samlede resultat for alle, der på det tidspunkt har besvaret, så man kan vurdere barnets trivselsniveau i forhold til den samlede gruppe. I kan også logge ind senere og se resultaterne efterhånden som flere og flere har besvaret.

Når man klikker på feltet, kommer man til spørgeskemaet (se appendiks C).

Når man klikker på <u>Voksen (plejeforældre eller ansat på opholdssted/døgninstitution)</u>, kommer følgende frem på skærmen:

Plejeforældre og ansatte på opholdssteder og døgninstitutioner har en vigtig og udfordrende opgave. Det er en stor gave at få kvalificeret hjælp af professionelle og en stor gave at kunne hjælpe – selvom det ikke altid er nemt – og det lykkes heller ikke altid. Oplevelse af nederlag og stress er desværre ikke ukendt.

Derfor får alle plejeforældre og ansatte på opholdssteder og døgninstitutioner i denne undersøgelse også mulighed for at fortælle lidt om, hvordan de har det. Formålet med undersøgelsen er at bidrage med viden, som kan være med til at forbedre hverdagen for børn og unge og plejeforældre og ansatte på opholdssteder og døgninstitutioner. Vi vil derfor gerne opfordre til, at *alle* voksne på anbringelsesstedet, som har kontakt med børn og unge, besvarer skemaet.

I toppen af spørgeskemaet skal du skrive dit CPR nummer. Det er der en bestemt grund til: Vi skal kunne sende et brev til dig på din adresse om et år ved hjælp af CPR registeret – med ønsket om, at du vil svare på de samme spørgsmål igen. Det er nemlig vigtigt at vide, om belastninger af plejeforældre og ansatte på opholdssteder mest er forbigående eller er mere vedvarende. Og det er kun muligt at få den viden, når oplysningerne med et års mellemrum "hænger sammen" – ved hjælp af CPR nummeret.

Med CPR kan vi desuden sikre, at dine svar ikke kan forveksles med andres svar, og vi kan gemme dine svar på en sikker server, så *ingen* – heller ikke forskerne - kan se dine personlige svar.

Af sikkerhedsmæssige årsager kan der ikke rettes i et skema, når det *er* sendt.

Når et spørgeskema er besvaret, kan du få vist det samlede resultat for alle, der på det tidspunkt har besvaret, så du kan vurdere dit eget trivselsniveau i forhold til den samlede gruppe. Du kan også logge ind senere og se resultaterne efterhånden som flere og flere har besvaret.

Klik <u>NÆSTE</u> (… så kommer man til spørgeskemaet, se appendiks C).

Appendix C: Questionnaires (in Danish)

Spørgeskema til børn > = 6 år ("Hvordan har du det?")

Det følgende bliver vist på skærmen, samtidig med at det høres:

Hej. Her er **17** små spørgsmål om, hvordan du har det. Du får et spørgsmål af gangen. Det er bedst, hvis du svarer helt selv, uden at nogen kikker. Hvis et spørgsmål er for svært, så går du bare videre til det næste.

Derefter vises et prøvespørgsmål. Og det vises og høres, hvordan man svarer. Derefter vises spørgsmålene et af gangen og svarmulighederne highlightes et af gangen. Til hver svarmulighed er der tekst, højtlæsning og smileys.

Smiley udseende tilpasses til hvert spørgsmål. 

Er du glad?	Ja, for det meste	Nogen gange	Sjældent
Er du ked af det?	Næsten aldrig	Nogen gange	Tit
Er du bange?	Næsten aldrig	Nogen gange	Tit
Er du sur?	Næsten aldrig	Nogen gange	Tit
Kan du finde en løsning, når noget er svært?	Næsten altid	Nogen gange	Sjældent
Kan du vente – til det bliver din tur?	Næsten altid	Nogen gange	Sjældent
Kan du godt li' dig selv?	Næsten altid	Nogen gange	Sjældent
Bliver du drillet, så du bliver ked af det?	Næsten aldrig	Nogen gange	Tit
Har du en voksen, du snakker med, når du har det svært?	Næsten altid	Nogen gange	Sjældent
Får du ros af de voksne, der hvor du bor?	Tit	Nogen gange	Sjældent
Føler du dig alene i verden?	Næsten aldrig	Nogen gange	Tit
Hvor tit har du hovedpine eller mavepine?	Næsten aldrig	Nogen gange	Tit
Er du træt?	Næsten aldrig	Nogen gange	Tit
Er det sjovt at lære?	Ja, for det meste	Nogen gange	Sjældent
Har du oplevet, at en voksen har holdt dig fast, for at du ikke skulle skade dig selv eller andre?	Aldrig	Nogen gange	Tit
Har du set, at en voksen har holdt andre fast, for at han/hun ikke skulle skade sig selv eller andre?	Aldrig	Nogen gange	Tit
Har en voksen hjulpet dig med at svare på spørgsmålene?	Nej	Ja	

Spørgeskema om børn >= 6 år, udfyldt af den nærmeste voksne.

Her bruges spørgeskemaet "Barnets styrker og svagheder", som er oversat fra Strength and Difficulties Questionnaire – et skema som er bredt anvendt i både Danmark og mange andre lande:

	Passer ikke	Passer delvist	Passer godt
Er hensynsfuld og betænksom overfor andre			
Er rastløs, 'overaktiv', har svært ved at holde sig i ro i længere tid			
Klager ofte over hovedpine, ondt i maven eller kvalme			
Er god til at dele med andre børn (slik, legetøj, blyanter)			
Har ofte raserianfald eller bliver let hidsig			
Er lidt af en enspænder, leger mest alene			
Gør for det meste, hvad der bliver sagt			
Bekymrer sig om mange ting, virker ofte bekymret			
Prøver at hjælpe, hvis nogen slår sig, er kede af det eller skidt tilpas			
Har mindst én god ven			
Kommer ofte i slagsmål eller mobber andre børn			
Er ofte ked af det, trist eller har let til gråd			
Er generelt vellidt af andre børn			
Er nem at distrahere, mister let koncentrationen			
Er utryg og klæbende i nye situationer, bliver nemt usikker på sig selv			
Er god mod mindre børn			
Lyver eller snyder ofte			
Bliver mobbet eller drillet af andre børn			
Tilbyder ofte af sig selv at hjælpe andre (forældre, lærere, andre børn)			
Tænker sig om før han/hun handler			
Stjæler fra hjemmet, i skolen eller andre steder			
Kommer bedre ud af det med voksne end med andre børn			
Er bange for mange ting, er nem at skræmme			
Gør tingene færdige, er god til at koncentrere sig			

Spørgeskema om børn < 6 år, udfyldt af den nærmeste voksne.

Hvordan oplever du, at barnet har det?

Er han/hun glad?	Ja, for det meste	Nogen gange	Sjældent
Græder barnet?	Næsten aldrig	Nogen gange	Tit
Virker barnet til at være bange/nervøs?	Næsten aldrig	Nogen gange	Tit
Er han/hun vred/hidsig?	Næsten aldrig	Nogen gange	Tit
Slår, kradser eller bider barnet andre børn?	Næsten aldrig	Nogen gange	Tit
Virker barnet nysgerrig og interesseret?	Næsten altid	Nogen gange	Sjældent
Hvor tit oplever du, at barnet har smerter, f.eks. hovedpine eller mavepine?	Næsten aldrig	Nogen gange	Tit
Er barnet træt?	Næsten aldrig	Nogen gange	Tit

Spørgeskema til de voksne på anbringelsesstedet, som er i kontakt med børn og unge. (spørgsmålene vises et af gangen på skærmen).

Oplever du, at dit arbejde kan være følelsesmæssigt belastende?	I meget ringe grad	I ringe grad	Delvist	I høj grad	I meget høj grad
Er dit arbejde meningsfuldt?	I meget høj grad	I høj grad	Delvist	I ringe grad	I meget ringe grad
Får du al den viden du har brug for, for at klare dit arbejde godt?	I meget høj grad	I høj grad	Delvist	I ringe grad	I meget ringe grad
Er du bekymret for at miste dit nuværende arbejde?	I meget ringe grad	I ringe grad	Delvist	I høj grad	I meget høj grad
Hvordan synes du, at dit helbred er alt i alt	Fremragende	Vældig godt	Godt	Mindre godt	Dårligt
Hvor stor en del af tiden i de sidste 4 uger:					
Har du været meget nervøs?	Hele tiden	Det meste af tiden	En del af tiden	Lidt af tiden	På intet tidspunkt
Har du følt dig rolig og afslappet?	Hele tiden	Det meste af tiden	En del af tiden	Lidt af tiden	På intet tidspunkt
Har du været trist til mode?	Hele tiden	Det meste af tiden	En del af tiden	Lidt af tiden	På intet tidspunkt
Har du været glad og tilfreds?	Hele tiden	Det meste af tiden	En del af tiden	Lidt af tiden	På intet tidspunkt
Har du være fuld af energi?	Hele tiden	Det meste af tiden	En del af tiden	Lidt af tiden	På intet tidspunkt
Har du følt dig træt?	Hele tiden	Det meste af tiden	En del af tiden	Lidt af tiden	På intet tidspunkt
Har du følt dig irritabel?	Hele tiden	Det meste af tiden	En del af tiden	Lidt af tiden	På intet tidspunkt
Har du haft smerter, f.eks. i hovedet, brystet, maven eller ryggen?	Hele tiden	Det meste af tiden	En del af tiden	Lidt af tiden	På intet tidspunkt
Har du haft svært ved at tænke klart?	Hele tiden	Det meste af tiden	En del af tiden	Lidt af tiden	På intet tidspunkt

Appendix D: 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.			