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## Randomized controlled evaluation of an internet-based minimal intervention delivery model for *The Resilience Program* - a mentalization-based health education program.

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### Abstract

In this study we have investigated the eventual impact of an internet-based minimal delivery model of *The Resilience Program* - a mentalization-based health education program which is freely accessible on the internet. Two target groups of vulnerable children and young people were selected for two parallel randomized controlled studies: Young adults diagnosed with ADHD (the ADHD trial) and children and young people taken into care (The care trial). In both trials the minimal delivery model consisted of a letter send to trial group participants with information about the Resilience Program.

**Results:** In the ADHD trial no significant changes in outcome measure were found as a result of the intervention. In the care trial there was found a possible long-term positive learning effect in children and young people in one of two intervention groups but no significant effect in the other intervention group.

**Conclusion:** We do not recommend further research into minimal delivery models of the Resilience Program. Based on results from this and other studies future program implementation and research should be directed toward specific (vulnerable) target groups with delivery models that involve regular staff training.

### Background

Resilience is defined as successful adaptation to adversity, including successful recovery from adverse life events and sustainability in relation to life challenges, individually and on group- and community-levels (Zautra et al., 2010).

At the very core of resilience is our capacity for thoughtfulness and careful thinking which is often needed in complex situations. That includes the skills of thinking about one's own

thoughts and feelings and the thoughts and feelings of other people as well as their connections with behavior. This is called *mentalizing* and is central in mutual understanding of relationships, self-control, motivation, and flexible understanding of what is going on in the world around (Fonagy et al., 2002; Fonagy and Bateman, 2011; Liotti and Gilbert, 2011).

*The Resilience Program* has been designed on the hypothesis that simple mental health education about mentalizing may help people to cope with complex challenges in life on individual, group and organizational levels. The Resilience Program is currently subject to a number of effect studies reported in this article and a parallel publication in which a thorough review of the background and the program is also presented (Lundgaard 2017).

The program can be found in Danish, English and Greenlandic versions here:

[www.robusthed.dk](http://www.robusthed.dk) and <http://myresilience.org/>. Short presentations of core modules from the program is also presented in Bak et al (2015). On the program website subsite ‘about us’ background review articles and research protocols can be found.

Preliminary results indicate that the Resilience Program<sup>1</sup> may have a positive impact on Theory of Mind development in school aged children (Valle et al, 2016), conflict prevention and reduction of staff sick leave (Bak et al, 2015). Hitherto experiences also indicate good program feasibility and compliance (Lundgaard Bak, 2012; Bak et al, 2015). Experiences and case stories illustrating the practical use of the program in various target groups is described in a book (Lundgaard Bak (ed.), 2018 in press).

As emphasized by Kadzin & Blase (2011) and Roth & Fonagy (2006) it is important that cost-efficient models of delivery in mental health care are developed in order to meet today's welfare challenges. For that reason - building up the evidence base about the program - we also investigate the eventual impact of the program using minimal intervention delivery models. In this article we present the results of a study with an internet-based minimal intervention delivery model. In another study the Resilience Program has been introduced to target groups (schools and educational institutions) in short lectures and courses. Results from this kind of minimal delivery model is published in a parallel publication (Lundgaard 2017).

Investigators have long tried to design and evaluate brief and self-directed interventions based on media technologies available – earlier mostly written materials, booklets and videos, more lately internet based interventions. Obviously because the internet is a tool with a potential for very large-scale dissemination of interventions (O’Connell 2009).

Meta-analyses of both pre-internet intervention studies (Montgomery, Bjornstad and Dennis 2006; Perkins et al, 2009) and internet-based interventions (Civljak 2010; Cushing & Steele 2010; Hedman et al, 2011; Sander, Rausch and Baumeister, 2016; Webb et al, 2010)

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<sup>1</sup> Formerly called “The Thoughts in Mind Program”.

indicate that this kind of brief, media-based, self-directed interventions can have small to medium sized effects and be cost-effective.

The aim of the research presented in this article is to investigate the eventual impact of an internet based minimal delivery model of the Resilience Program on selected target groups of vulnerable children and young people. Two target groups were selected:

1. Young people with ADHD.

ADHD affects in the order of 1 in 20 children and young people although figures vary over time and location and depends on the diagnostic criteria used (Faraone 2003, Center for Disease Control 2017).

A Cochrane systematic review suggest that there is need for more intervention trials, with low risk of bias and with a sufficient number of participants, investigating the efficacy of social skills training for children and adolescents with ADHD (Storeboe et al, 2011). The same holds for family therapy (Bjornstad and Montgomery, 2005).

No trials has, to our knowledge, investigated potential effects of mentalization-based mental health education for people with ADHD.

2. Children and young people taken into care.

Children and young people taken into care (foster care and residential care) are in a vulnerable life situation. Otherwise they would not have been taken into care. According to UNICEF the prevalence of foster care and residential care and the reasons why children and young people sometimes lose their first line of protection – their parents, and eventually are taken into public care, vary widely across the world (UNICEF, 2017).

Training programs for foster carers have proliferated but there has been minimal evaluative research and no evidence for effectiveness of this kind of programs (Turner, McDonald and Dennis, 2007).

The protocol for a two-arm, randomized control feasibility trial investigating the acceptability and credibility of mentalization-based treatment (MBT) as a treatment for reducing emotional and behavioral difficulties in looked after children was published in February 2017 (Midgley et al, 2017). This study also address a number of methodological challenges to conducting high-quality research with this population. This is, to our knowledge, the only hitherto existing study which explore the potential effect of a mentalization-based approach with this vulnerable population.

With the two current minimal intervention studies, we also exploit the opportunities of using administrative (register) data as outcome indicators - as recommended by the Coalition for Evidence Based Policy (2012).

## Materials and Methods

The trials in the research projects are designed to follow the CONSORT Criteria for randomized controlled trials and 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). The trials were approved by relevant Danish authorities.

### The ADHD trial

This study is a randomized controlled trial conducted within guidelines for pre-consent randomization trials (McRae et al, 2011). The study population included all persons aged 18-27 year who on a specific date in august 2014 were registered with a diagnosis of Attention Deficit Hyperactivity Disorder in the Danish National Patient Register<sup>2</sup>. Patients with requested protection against contacts from researchers and patients whose address couldn't be identified were excluded. The study population consists of 7821 individuals. The study population was computer randomized into an intervention group and a control group.

A letter with an invitation to participate in the study was send in august 2014 to all patients, whose addresses were obtainable<sup>3</sup>.

The first part of the letter to participants *in both trial groups* was an invitation to participate in an electronic survey about Mental Health. The patients were encouraged to log in on a website with a unique code if they wanted to answer the questionnaires. Moreover, the participants were asked if they wanted to answer monthly follow-up questionnaires. If so, the participants were asked to write their email-address the first time, they answered a questionnaire. In the following 12 months, this group of participants received a reminder email every month, encouraging them to fill out the electronic questionnaires.

Patients in the control group got no further information.

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<sup>2</sup> With permission researchers can use the Danish civil registration number (CPR-number), which is a unique 10-digit identification number for citizens in all Danish registries. By using the CPR number as linking variable researchers can collect health data and socioeconomic administrative data on the same person from different registries (Lynge 2011).

<sup>3</sup> The CPR-numbers of the patients were linked to the patients' postal addresses by the Data Management Unit at the Department of Public Health, Aarhus University.

In the letter send to participants *in the intervention group* they were also given information about the Resilience Program, a link to the program and an invitation to participate in a public lecture at the library in a nearby city. Lectures were held in 14 cities geographically distributed in Denmark. To secure patient anonymity other groups were also invited to the lectures (staff from the care trial and staff and parents from randomly selected local public schools). This constitutes the minimal intervention of the ADHD trial.

### **Outcome measures in the ADHD trial**

Participants were asked to fill out two small questionnaires:

- General health questionnaire (GHQ12): A 12 items questionnaire that measure common dimensions of mental well-being (Jackson, 2007).
- ADHD Self Report Scale (ASRS): A 6 items questionnaire covering the most predictive symptoms of a diagnosis of ADHD in DSM-IV (Adler, 2011).

Moreover, the participants were asked, whether they received any medical treatment or any psychological treatment of the ADHD.

Receipt of social benefit was also used as outcome measure. This measure is assessed for all Danish citizens on weekly basis in the municipalities. Data are collected in the social registry called DREAM. If a person has received a given benefit for one day the register shows this benefit for the whole week. If a person changes from one benefit to another within one calendar week, there is a priority matrix saying which benefits overrules others.

In the original research protocol questionnaire data was planned as primary outcome variables. Because the questionnaire response was very low, receipt of social benefit in 2016 was instead used as primary outcome measure. Data on this measure was available for all participants.

### **Statistical analysis in the ADHD trial**

Differences between the intervention and the control group, in terms of receipt of social benefit, were analyzed using unpaired t-test. The differences were analyzed one and two years after baseline, respectively. These analyses were performed both on the entire study population, and on the subpopulation of participants who had answered the questionnaire at baseline.

Differences between the intervention group and the control group with regard to the questionnaire data were analyzed with unpaired t-test as well.

### **The care trial**

This study is a cluster randomized controlled trial conducted within the guidelines for pre-consent randomization trials reviewed by McRae et al (McRae et al, 2011). The study population included all children and young people under the age of 18 who were registered in a national registry as being in foster care or residential care on a specific date in August 2014. Persons with requested protection against contacts from researchers were excluded. The study population consists of 9114 individuals age 0-17 years. The study population was cluster randomized by a computer program into two intervention groups and a control group using the care place as cluster variable so all children in one care place were assigned to the same trial group.

A letter with an invitation to participate in the study was sent in August 2014 to all participant care places, whose addresses were obtainable. The first part of the letter to participants in both trial groups and the control group was an invitation to participate in an electronic survey about Mental Health. The patients were encouraged to log in on a website with a unique code if they wanted to answer the questionnaires. The professionals at the care place were asked to answer questions about the mental health of the children: The Strength and Difficulties Questionnaire. They were also asked to answer a questionnaire about their own wellbeing: The General Health Questionnaire (Jackson, 2007).

Participants in the control group got no further information.

In the letter sent to participants in *intervention group 1* they were also given information about the Resilience Program and a link to the program. In the letter sent to participants in *intervention group 2* they were given information about the Resilience Program, a link to the program *and* an invitation to participate in a public lecture at the library in a nearby city. Lectures were held in 14 cities geographically distributed in Denmark. To secure anonymity other groups were also invited to the lectures (young people from the ADHD trial and staff and parents from randomly selected local public schools). This constitutes the minimal intervention of the care trial.

### **Outcome measures in the care trial**

The questionnaire response rate was so low that it was meaningless to use the data for efficiency evaluation. As primary outcome measure national school test results in Danish reading for the school aged children enrolled in the study were used as an indicator for their academic performance and wellbeing. Staff sickness leave in residential institutions enrolled in the study was used as an indicator of staff resilience. This measure is also monitored on national level in the DREAM database mentioned above. Data on foster care parents sick leave was not available at the time of the study.

## Trial Registration

Clinicaltrials.gov ID numbers: The ADHD trial: NCT02220140. The care trial: NCT02220179.

## Results

### The ADHD trial

Results from the analysis of data from the ADHD Trial is shown in figure 1. There is no statistically significant difference between the trial group and the control group as a result of the intervention.

Figure 1: Statistical analysis of outcome data from the ADHD trial – the average number of weeks participants has received social benefit in 2016.

<b>N=7297</b>	Intervention	Control	p-value for difference between groups
All; Number of weeks Social benefit 2016	0,36	0,42	0,40
Women; Number of weeks Social benefit 2016	0,46	0,49	0,84
Men; Number of weeks Social benefit 2016	0,31	0,38	0,36

### The care trial

Data on test results in Danish reading in the school year 201/2016 were available for 413 participants in the control group, 369 participants in intervention group 1 and 399 participants in intervention group 2. Data fulfilled assumptions about homogeneity. There was a statistical significant difference between groups as determined by one-way ANOVA ( $F(2,1178) = 3.59, p = 0.028$ ). A Tukey post-hoc test showed that the performance was significantly lower in the control group compared to intervention group 2 ( $-4,16 \pm 1,74$

points,  $p = 0.044$ ). There was no significant difference between intervention group 1 and the control group ( $-0,17 \pm 1,77$  points,  $p = 0,995$ ).

Data on sick leave for residential institution staff in 2016 was available for 349 individuals. A nonparametric Kruskal-Wallis test was performed to see if there were any significant differences between the three randomization groups. The results are shown in figure 2. There are no significant difference between sick leave frequency in the three groups.

Figure 2: Statistical analysis of average sick leave (number of weeks per person) among residential institution staff in the three randomization groups.

N=349	Intervention 1 (n=129)	Intervention 2 (n=111)	Control (n=109)	p-value difference
Sick leave, weeks, 2016	0,74	0,49	0,86	0,64

## Discussion

In this study, we have investigated the impact of a mentalization-based mental health education program – The Resilience Program - with an internet-based minimal delivery models in 2 different settings: Young people diagnosed with ADHD and children and young people taken into care.

From a public health perspective there are good reasons why minimal delivery models for health education programs seems attractive (effectiveness, mass distribution, health economics). Thus, when new types of programs are developed – as The Resilience Program - minimal delivery models should be part of the investigation and evidence base for the program.

The strength of the study was limited because questionnaire response rate was very low so we had to change the primary outcome measure and because the availability of outcome data was lower than anticipated. However, this was equally distributed in all randomization groups.

In the ADHD trial of this study no significant changes in outcome measures were found as a result of the intervention. In the care trial children in intervention group 2 performed statistically better in the national test in Danish reading after the intervention than children in the control group. However, intervention group 1 children did not perform significantly different from children in the control group. In both intervention groups foster carers and residential institution staff had received a letter with information and a link to the Resilience Program website. Intervention group 2 additionally received an invitation for an open



lecture about the program in a local library. We don't know how many attended the lectures because other groups of people were invited for the sake of anonymity. Apparently, the significant result in intervention group 2 is a strong result considering that we talk about a very minimal intervention, a long follow-up period and an outcome measure related to the children's school performance with an intervention directed towards their home environment. However, one has to be very cautious about conclusions. No significant improvement was found in intervention group 1 which only differ slightly from intervention group 2. Also staff sick leave - as an indicator of their resilience - was not affected. It would be a reasonable hypothesis to expect such changes in resilience markers when improvements in the children's learning capacity was detected. Moreover, this is the first of this kind of study, so in principle the results have to be reproduced in other independent studies before firm conclusions can be drawn.

In the parallel study in which a minimal delivery model was applied to schools and educational institutions in the form of short introductory lectures we found no significant effects of the intervention (Lundgaard 2017). In this article we thoroughly discuss the potential reasons for this kind of negative and weak results. Based on the results from the current two studies we cannot recommend further research into minimal delivery model implementation of the Resilience Program. At the same time the results from the current studies and other studies justify continued research by independent research groups to evaluate eventual program effects *in specific (vulnerable) target groups with delivery models that involve regular staff training*.

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