Project description 'Brave Steps: A Stepped-Care Approach to Building Confidence in Anxiety-prone Young Children'

1. Problem definition and Objective

Currently, our research group is examining the effectiveness of the CLK intervention as a prevention program for children who are prone to anxiety but have not yet met the criteria for a psychiatric disorder (treatment/step 2 in this project). However, during the screening process and in our communication with mental health care services, we have observed a sizable group of children who have more serious problems and already meet the criteria for an anxiety disorder but have not been referred to specialized health care yet (treatment/step 3 in this project). At the same time, there are also anxiety-prone children who possibly could benefit from lighter care such as a parental webinar with psychoeducation and online knowledge clips (treatment/step 1 in this project). This could also be suited for parents who are less motivated, unable to participate due to their busy schedules, or are less likely to participate in a group intervention. In such cases, a parental webinar with psychoeducation and online knowledge clips could be a viable solution and could help lower the threshold for participation in subsequent steps of the intervention.

However, this stepped-care treatment program in early childhood for anxiety-prone children does not exist yet in The Netherlands. To address the needs of all these groups, we propose a stepped-care treatment approach. The effectiveness of this approach will be examined in anxiety-prone toddlers aged 3-6 years in the Netherlands, in collaboration with the Public Health Service (GGD) Amsterdam and Groningen, a Amsterdam-based mental health care organization (MOC 't Kabouterhuis), a Rotterdam based mental health care organization (Indigo) and a The Hague based mental health care organization (Youz).

In summary, this project aims to

a) develop a stepped-care treatment approach for parents of anxiety-prone young children,

b) examine the effectiveness and cost-effectiveness of this approach, and

c) assess parents' satisfaction

2. Design

In a randomized controlled trial parents of anxiety-prone children will be allocated to either the stepped-care treatment program condition or to a 'care as usual' condition. A screening, an assessment, and three follow up assessments (post-measurement immediately after, 12 and 24 months after the end of the stepped-care treatment program will be conducted.

3. Recruitment and participants

The first step involves screening for young children at risk of anxiety disorders with the Behavioral Inhibition Questionnaire-Short Form (Vreeke et al., 2012). This Dutch screening questionnaire has

proven to be valid and reliable in detecting anxiety-prone toddlers. This screening is done by the Public Health Service (GGD) in Amsterdam and Groningen, who have already implemented the Behavioral Inhibition Questionnaire-Short Form in 'Jij en je Gezondheid (JEJG)', an online system to screen children on social and emotional problems. Parents of children aged 3-6 years visiting the Public Health Service will be asked to complete the BIQ-SF in this online screening tool. Parents of toddlers scoring above the BIQ-SF cut off norms (which were derived from the large community sample of Dutch children studied by Vreeke et al. (2012) are contacted for participation in the project.

A sample size of 250 participants is estimated to provide power of 0.8 to detect a significant difference ($p < .05$) based on a difference between groups of $d > 0.3$. Based on the JEJG data completed in school year 2021-2022 there were 897 children with an elevated score on the BIQ-SF in the Amsterdam region of the 3346 children for whom the questionnaire was completed. Therefore, the planned number of 250 participants will be feasible. Since we screen in the big cities of the Netherlands in which > 50% of the population has a migration background (CBS, 2023), the sample will include children with a migration background as well as children of Dutch descent.

Once a child has been identified as scoring high on the BIQ-SF screening measure, a clinical interview will be conducted with the Diagnostic Infant and Preschool Assessment (DIPA; Gigengack et al., 2020) to determine the severity of the social and emotional problems and the appropriate treatment.

1. **Stepped-care treatment approach**

The treatment plan will consist of a stepped-care treatment approach of evidence-based interventions with elements of cognitive behavioral therapy (CBT) and exposure therapy. This approach would ensure that all children receive the necessary level of care, and that parents who are less able to engage are still able to participate in the intervention to some extent. By providing the least intensive intervention necessary, we aim to tailor treatment to the individual needs of each child. Our approach will involve three levels of intervention, parents of children identified as inhibited based on the BIQ-SF screening questionnaire from the previous ZonMw study will receive based on their needs 1) CLK Light: webinar and knowledge clips explaining anxiety problems and guidance on helping and non-helping parental responses 2) the preventive Cool Little Kids parent intervention program or 3) Cool Little Kids Plus, an extended version of CLK suited to treat anxiety disorders.

1) To lower the threshold for parents who may be less engaged or find it difficult to participate in a group session, we propose a one-evening parenting webinar combined with individual online knowledge clips as the first step of the stepped-care treatment approach. The focus of the webinar will be on psychoeducation and providing guidance on helpful and unhelpful ways of parental response to withdrawn, fearful behavior in children. In addition, we aim to develop several animations (knowledge clips) in which psychoeducation is given which may also be offered in other languages and with Dutch subtitles, to reach an even larger group of parents.

Research has shown that parental engagement is crucial for the success of preventive interventions, making it important to provide options for parents who may find it challenging to participate (Mian,

2014). The parenting webinar combined with individual online knowledge clips could help to lower the threshold for participation in subsequent steps of the intervention. This CLK Light treatment can be given by prevention workers from the municipal health care services ('consultatiebureau'), with a close line to specialized health care.

2) The CLK intervention (Rapee et al., 2005), a six-session parent-focused preventive intervention for reducing anxiety and associated impairment in at-risk children. The program uses Cognitive Behaviour Therapy (CBT) techniques, which has been proven to be the most effective technique in reducing anxiety problems, to provide parents with effective tools and strategies to assist their child. Topics of the program include psychoeducation, helpful and unhelpful ways of responding to anxiety in children, skills and strategies for exposure. The intervention consists of 6 group sessions across a 6-8 week period, held at the same time each week. Each session runs for approximately 2 hours. Australian studies have indicated that the CLK parent-education intervention for young anxiety prone children aged 3 to 6 years is very effective in reducing anxiety symptoms. That is, parents of behaviorally inhibited children participating in the program reported a significantly greater decrease in anxiety disorders at 12-, 24-, and 36-month follow up as compared to controls (Rapee et al., 2005). Most importantly, the intervention had long-lasting effects; an 11-year follow up indicated that especially girls whose parents had received the intervention continued to demonstrate fewer anxiety disorders (61% compared to 38% in the control group) and lower levels of anxiety symptomatology at age 15 (Rapee et al., 2013). The license to perform this program in the Netherlands has already been acquired, and the study to examine the cost-effectiveness of this intervention is almost finishing up. This CLK treatment is given by prevention workers working at specialized health care.

3) Individualized treatment. In collaboration with Ron Rapee, the developer of the CLK program, we aim to expand the CLK program to a clinical variant. This program will be given individually instead of in a group, will contain more sessions and will add more CBT elements than the preventive CLK program. In this way, parents will receive more specific, tailored care. This CLK Plus treatment is given by prevention workers working at specialized health care.

During this project, the CLK Light (treatment 1) and the CLK Plus program (treatment 3) will be further developed, pilot tested and adapted based on these first results in collaboration with the Australian professor Ron Rapee.

2. Outcome measurement stepped-care treatment model

To examine the successful implementation of the stepped-care treatment model, we assess the number of individuals who have participated in the various stages of the intervention, that is: those who participated in CLK Light, CLK and CLK+, and compare these numbers with the number of individuals seeking help in the control group. In this way, we would be examine whether we reached groups that have not yet received adequate care yet.

To assess this outcome measure we asses children's developmental and psychiatric problems. These parameters will be assessed using multiple informants (child, parent and teacher) and multiple

methods (interviews, questionnaires) at pre-intervention, post-intervention, 6 and 12 months follow up. Parents fill out the Preschool Anxiety Scale-Revised (PAS-R) and will be interviewed by a clinician blind to group allocation to assess child internalizing diagnoses with the Diagnostic Infant and Preschool Assessment (DIPA; Gigengack et al., 2020). Teachers fill out the School Anxiety Scale—Teacher Report (SAS-TR) and the 'anxious-depressed' subscale of the Teacher Report Form (TRF). Children will fill out the Koala Fear Questionnaire (KFQ; Muris et al., 2003), a self-report interview instrument measuring anxiety in children of 31 potentially fear-provoking stimuli and situations that are common in young children (e.g., “the dark”, “thunderstorms”, “lions”, “ghosts”).

It is expected that children from the stepped-care treatment group would receive more official diagnoses since their parents would seek help more often, however it is also expected that their social and emotional symptoms would be less severe. Conversely, the control group would likely exhibit less help-seeking behavior, fewer diagnoses, but an equal or greater number of complaints.

3. Secondary outcome measures

Secondary study parameters are parental internalizing problems and parent behaviors. Parents of anxiety prone children often experience internalizing problems themselves, and model their anxious behavior to their children (e.g., Bögels & Brechman-Toussaint 2006). In addition, these parents tend to use parenting behaviors such as being overprotective to their anxiety-prone or anxious children (often augmented by the parents’ own anxiety (see de Vente et al., 2011). By taking over tasks of their child or restrict its exposure to a broad range of situations, these parents possibly enhance the child’s behavioral inhibition across development, ultimately increasing the risk for developing an anxiety disorder (Rubin, Burgess, Kennedy, & Stewart, 2003). These parameters are measured by two parent questionnaires at pre-intervention, post-intervention, 6 and 12 months follow-up. The Parental Overprotection Measure (POM; Edwards, 2007) will be used to measure parenting behaviors, the Spielberger State–Trait Anxiety Inventory (STAI; Spielberger, Gorsuch, & Lushane, 1970) and the Beck Depression Inventory (BDI, Beck, Ward, Mendelson, Mock, & Erbaugh, 1961) will be used to measure parental anxiety and depression.

4. Economic evaluation

The evaluation of cost-effectiveness will be done by examining costs and effects of the stepped-care treatment group versus the ‘care as usual’ group (Bodden et al., 2008). Quality of life questionnaires () and a cost-dairy will be filled out by parents at pre-intervention, and 1- and 2-year follow up. The cost analysis will include direct healthcare, direct non-healthcare, indirect and out-of-pockets costs. The cost analysis will be performed from a mental healthcare perspective and societal perspective.

5. Moderators

The possible moderating role of parental gender and child gender on the effectiveness of the intervention will be examined, as well as parental educational level, parental engagement and migration background.

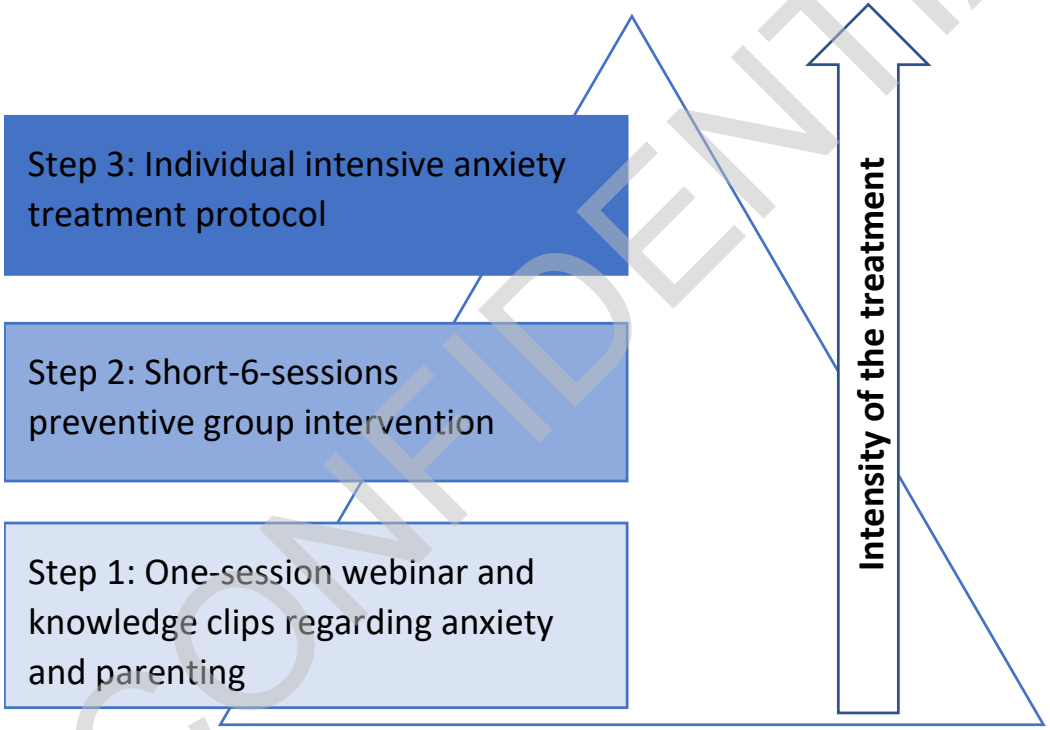

Figure 1. schematic overview of the stepped care approach in the Brave Steps project

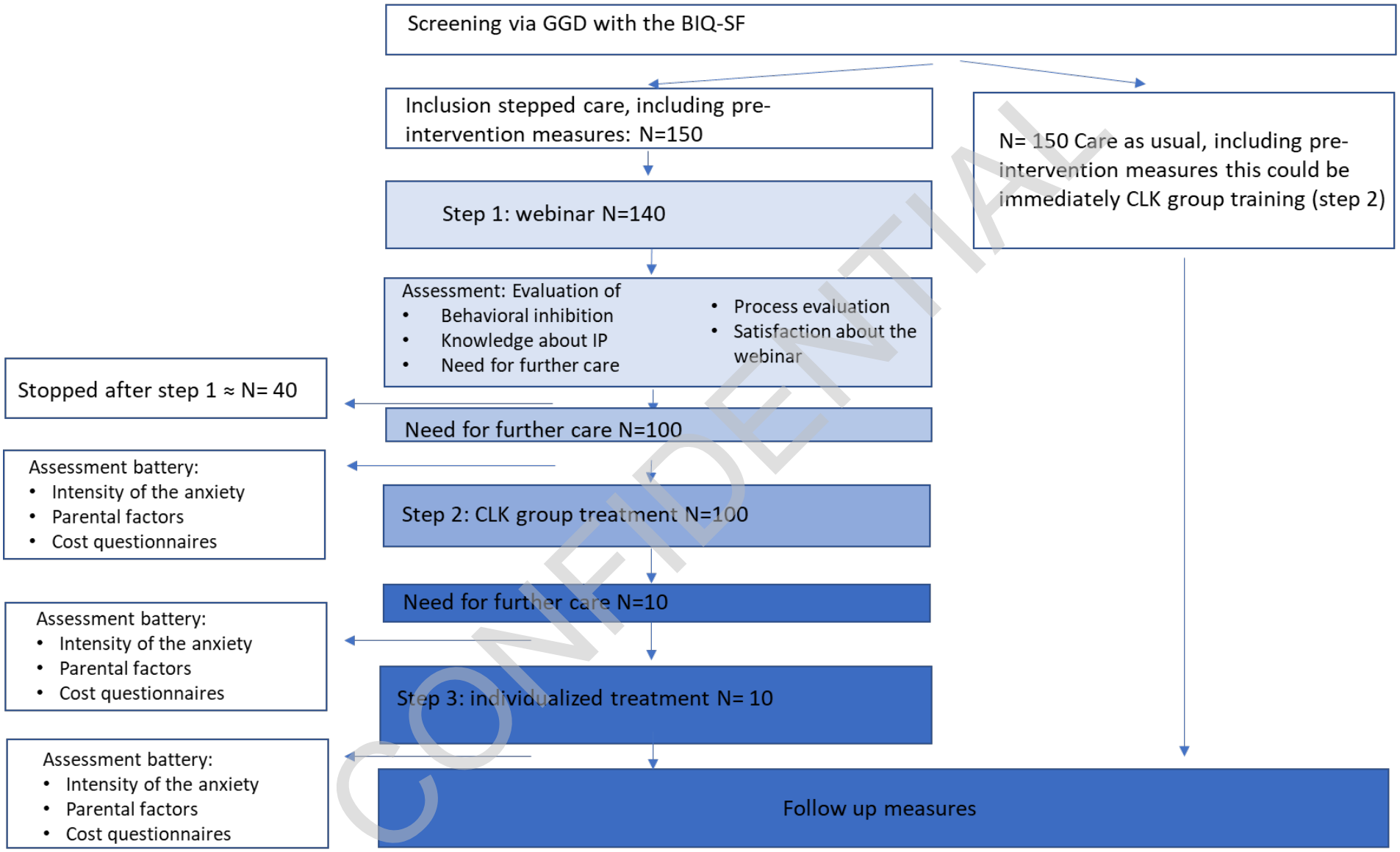

Figure 2. Participant flow chart of the Brave Steps project. Note: IP = internalizing problems