A randomized controlled trial on the effectiveness of a sexual abuse prevention programme for girls with intellectual disabilities: study protocol

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ABSTRACT

Objective: Sexual abuse is reported to be more prevalent among children with intellectual disabilities (ID), which emphasizes the need for preventive measures to be taken. The few studies on prevention programmes show methodical weaknesses, such as small sample sizes, a lack of a control group, or invalid outcome measures. This study aims to develop and evaluate a sexual abuse prevention programme that is tailored to the needs of girls with ID and that eliminates many of these weaknesses.

Method: The study will enrol 120 girls aged 8–12 with mild ID recruited at special schools. After block randomization, the effects of the prevention programme will be examined in a controlled four-time follow-up design. Preventive skills will be assessed in terms of individual changes in measures of knowledge, verbal reports of anticipated behaviour, role plays, and in situ probes. In situ probes will assess participants’ behaviour in a realistic setting, with participants being unaware of the evaluation. All assessments will be videotaped and rated by blind raters.

Discussion: This study will be the first randomized controlled trial on the effectiveness of a prevention programme for girls with ID using valid outcome measures with a large sample. It will meet the criteria established for evaluation studies of prevention.

1. Introduction

Research on the prevalence rates of sexual abuse and the severity of consequential damages underlines the need for prevention programmes aimed at adults and children with intellectual disabilities (ID) (Lee & Tang, 1998). Generally, the risk of being sexually abused is higher for individuals with ID, even more so if they live in an institution (Euser, Alink, Tharner, van Ijzendoorn, & Bakermans-Kranenburg, 2016). In Germany, the rate of abuse among women with ID is 2–3 times higher than that for women from the general population (Bundesministerium für Familie, Senioren, Frauen und Jugend [BMFSFJ], 2013). Sexual abuse often occurs early in life, as shown by Baladerian (1991); in this review, 83% of women with ID were abused before their 18th birthday.

The increased vulnerability to sexual abuse among individuals with ID is due to many risk factors (Muccigrosso, 1991; Tang & Lee, 1999), such as lower degrees of sexual knowledge, social competence, and the ability to judge and to report. Additionally, individuals with ID have more social needs and are more likely to subordinate to staff persons, such as caregivers (Kim, 2010). They tend to be more isolated and may be life-long dependent on caregivers, who make up a large proportion of sexual offenders (see Barger, Wacker, Macy, & Parish, 2009). This presents severe challenges for individuals living with ID. More than 95% of them who experienced sexual abuse suffered from mental health problems, such as social withdrawal, feelings of guilt, aggression, less self-confidence, behaviour problems, and deviant sexual behaviour (Mansell, Sobsey, & Calder, 1992). Individuals with ID are also more likely to experience chronified victimization than individuals without ID (Mansell et al., 1992; Sobsey & Mansell, 1994; Tang & Lee, 1999). However, sexually abused individuals with ID often suffer from a prolonged denial of their abuse, from inadequate access to treatment services, and from a paucity of appropriately trained professionals (Mansell et al., 1992). This seems to be even truer for children and adolescents (Seligmann, 1996).

An approach to enhance prevention for this at-risk group is to train individuals with ID to recognize and endure at-risk situations. Eight studies on adults with ID and five studies on children and adolescents with ID investigated such an approach (listed in Chodan, Häßler, & Reis, 2014, except for Kim, 2016). Several reviews (Barger et al., 2009; Bruder & Kroese, 2005; Chodan et al., 2014; Doughty & Kane, 2010; Lumley & Miltenberger, 1997; McEachern, 2012; Muccigrosso, 1991; Tsui, 2008) acknowledged the benefits of such an approach while also identifying several...
shortcomings of these specific programmes and their evaluation studies. Points of criticism are listed below.

- Many programmes have not yet been evaluated in randomized controlled trials. For Germany, not a single evaluation study was reported.
- Some programmes were not tailored to the special needs of people with ID.
- Most programmes addressed individuals with ID aged 20 or older, whereas the majority of victims were found to be younger than 18 years at the time of their first abuse (Baladerian, 1991).
- Programmes did not include offenders with a close relationship to the victim, even though they make up the majority of offenders (Mazzucchelli, 2001).
- Evaluation studies used small samples only, thus not allowing them to rule out random effects.
- Many studies failed to investigate whether positive effects generalize to real-life situations of sexual abuse. A recent exception is the study of Kim (2016) wherein participants were exposed to seduction in different naturalistic situations.
- Other outcome variables were questionable in many studies because the reliability and validity of data from questionnaires or interviews were low or unproven.
- In several studies, effects were not judged by independent or blinded raters.

As a consequence, several authors called for further prevention programmes and evaluation research (e.g., Haseltine & Miltenberger, 1990; Sobsy & Mansell, 1994; Tang & Lee, 1999), especially for children (Watson, Bain, & Houghton, 1992). Lumley and Miltenberger (1997) provided a list of important issues to consider regarding individuals with ID: (1) Training should address specific needs and abilities of the target group, such as mental ability and sexual maturity; (2) Training should address various types of lures, locations, and perpetrators; as well as (3) various sexual abuse prevention skills, including knowledge and behavioural skills, such as appraisal, refusal, escape, and report; (4) Training procedures should comprise instructions, modelling, prompting, rehearsal, praise for correct performance, and training in situ; (5) Programmes should be carefully evaluated, assessing prevention knowledge and prevention skills; (6) Sexual abuse prevention skills should be charged using role-play assessments and in situ probes; (7) Evaluation should include social validity assessments of training procedures and outcomes; (8) Prevention programmes should promote maintenance using booster sessions; (9) Programmes and evaluation studies should comprise periodic in situ assessments. In the authors’ view, these ideas need to be specified for children and adolescents with ID.

Programmes that use a cognitive approach – which has been proven effective in adults with ID (Hickson, Khemka, Golden, & Chatzistyli, 2015; Khemka, 2000; Khemka, Hickson, Reynolds, & MacLean, 2005) – require insights and a faculty of abstraction that exceeds the abilities of children with ID (see Lösel & Beelmann, 2003, 2006). Thus, an approach that focuses on behavioural aspects should be favoured over a solely cognitive approach. Both are essential for sexual abuse prevention: while the behavioural chain is needed to react in the situation of a sexual abuse lure, theoretical knowledge is needed to understand the situation in the first place and to report it adequately to a trusted person. For example, children with ID need to know the names of private parts. To our knowledge, four studies successfully applied behavioural skills training to children with ID (Kim, 2016; Llewellyn & McLaughlin, 1987; Tang & Lee, 1999; Watson et al., 1992), which encourages us to try a similar approach. To do so, not only the programme but also the assessments in this study need to be adapted to the needs of the specific target group, including their age and mental status. Several specific recommendations were derived from the literature, such as the measurement of sexual knowledge through a board game. Several ideas guided us. Playful interventions are more appealing than questionnaires to children with ID (Hoogeveen, Smeets, & Lancioni, 1989). Answering questions in the course of a board game that is similar to well-known games and toys should ensure familiarity and enhances the stimulative nature of the assessment, evoking more reliable and valid outcomes than questionnaires or interviews (Innerhofer, 2013, p. 97). This kind of game is less dependent on verbal skills and thus is better suited to children with ID, who often suffer from low verbal skills (Wirth, 2000, p. 740). To ensure the feasibility and safety of the programme and measurements, several focus groups with experts from the field and a pilot study are planned.

1.1. Aims and objectives

The study introduced here aims to fill several of the gaps listed above. A structured manualized group training programme ‘EMMAunantastbar!’ (Emma untouchable) will be developed by focusing on girls with ID between the ages of 8 and 12 years. The goals of the project are the following:

- To provide a sexual abuse prevention group programme that can be easily disseminated and that is tailored to the developmental and cognitive characteristics of girls with ID aged 8 to 12 years,
- To evaluate this programme with a sample of girls with ID in a RCT-design applying highly valid measurements, and
- To carefully consider and pursue the demands postulated by Miltenberger and Olson (1996, in Lumley
and Miltenberger (1997) throughout the development, implementation, and evaluation of the programme.

2. Methods

The evaluation study will employ a randomized control group design in which an intervention will be compared to a sham intervention with four points of measurement (pre-post follow-up and a fourth after a booster session; see Fig. 1). Data will be gathered at four points of measurement: (1) before the group training, (2) after the group training lasting 10–12 weeks, (3) at a follow-up 3 months after the end of training, and (4) after a booster session was applied to a subsample of the intervention group 1–2 weeks after the third measurement. Group comparisons will be made to check for group training’s effectiveness.

The study is planned for three study sites (University of Rostock, kbo Heckscher Clinic Munich, and Wildwasser Munich e.V.). The first site – a clinic for child and adolescent psychiatry at a university – will function as the study centre. The second site will be represented by a community-funded psychiatric hospital for children and adolescents. The third site will be a non-governmental organization providing sexual abuse prevention programmes.

2.1. Power analysis and data analysis

Comparisons will be made between the intervention group and control group using baseline-controlled repeated ANOVAs with the four measures (board games, verbal reports, role plays, and in situ probes) as dependent variables and the experimental condition as the independent variable. We hypothesize that the intervention group will show higher levels of prevention knowledge and skills than controls after the intervention programme, which will be significantly enhanced by a booster session. To discover these effects, we began to calculate sample sizes at the right end of the design, with a t-test of the effect of the booster session. Unfortunately, the literature provides no hints on effect sizes. To discover a rather large effect (assuming an effect size of 0.7 considering a short interval of a week between $t_3$ and $t_4$ with a power of 0.8, 26 subjects per group are needed when setting the $\alpha$-error to 0.05 (Faul, Erdfelder, Lang, & Buchner, 2007). Adding an estimated 15% drop-out rate, two groups of 30 persons from the intervention group should be randomized after the third measurement. Calculated backwards from there, this kind of sampling gives us the power to detect effects of a medium size (0.31) for a MANOVA with a repeated measurements design for the interaction of the group factor (intervention vs. sham intervention) and time (three points of measurement, $t_1$–$t_3$ on $n = 104$ subjects. Adding an estimated drop-out rate of approximately 15%, we ended up with a total needed sample size of $N = 120$.

2.2. Independent variables and recruitment

Girls with mild ID (IQ 50–70) or a comparable severity of cognitive disabilities aged 8–12 years will be included in the study. This age range was chosen in order to exclude girls who were sexually mature, who would make the groups less homogenous in this regard. Exclusion criteria comprise pervasive developmental disorders (autism) and severe acute psychiatric disorders (see Lee & Tang, 1998).

The level of intellectual functioning will be assessed with the Wechsler Nonverbal Ability Scale (WNV; Wechsler & Naglieri, 2006), unless IQ has been assessed by a certified psychologist/child psychotherapist with a recognized intelligence test within the past 3 years. Additional records will be checked, if available, to obtain more

![Fig. 1. Study design for the evaluation study. R = Randomization, K & S = Knowledge and Skills, SV = Social Validity (acceptance and unwanted effects). Sample sizes are made according to the power analysis and compensate for the anticipated attrition (in brackets).](image)
differential information about various disabilities. Participants’ speech-processing ability will be assessed as a covariate using the Trog-D (Fox, 2013). To control for comorbid mental health problems, the Child Behaviour Checklist (CBCL; Achenbach & Rescorla, 2000) will be completed by parents or guardians at the time of enrolment. At this time, data on family structure, social risks of various kinds (including previous events of sexual abuse), and stage of sexual maturity (Tanner scales; Marshall & Tanner, 1969) will be collected.

The recruitment of subjects will follow a 2-step process. In a first step, schools that enrol students with ID will be approached, and a presentation of the study will be given to the school administration and staff. After obtaining the school principal’s permission, the school’s staff will send out an invitation letter to all parents of girls aged 8–12 years. A brief overview of the study containing details about data procession and data protection will be given to parents. In a second step, more details will be provided at a parent–teacher conference about the study in a standardized presentation. Informed consent of voluntary participation will then be collected at the conference or by mail. All parents will be informed about their right to withdraw their consent at any time with no need for justification. An expense allowance for participating in the evaluations study will be offered to parents: 50 euro at the beginning of the study and another 100 euro after completion of the study. Included will be expenses for transporting the girls to different study locations.

2.3. Measurement of dependent variables

In this study, two constructs are modelled as dependent variables, namely, sexual abuse prevention knowledge and sexual abuse prevention skills. This theoretical distinction was made by the authors and needs empirical support. The former will be measured via a structured interview (embedded in a board game) and a verbal report of anticipated behaviour given by the participants in reaction to a scene from a video clip. Behavioural prevention skills will be operationalized by interactions with the trainer within role plays and with alleged offenders during in situ probes.

(1) Prevention knowledge: Board game. Sexual knowledge will be assessed using a board game. In playing the board game, participants will answer questions on sexual abuse, such as naming the private parts or differentiating between appropriate and inappropriate touch using an objective rationale (e.g., ‘It is forbidden for a teacher to touch a girl’s private parts’) and a subjective rationale (‘I dislike this touch’). Participants will not receive feedback on the correctness of their answers but will instead move forward on the board after each question, regardless of whether their answer is correct. Items in the game will be specifically designed for the purpose of the study and will encompass (and exceed) questions from the Personal Safety Questionnaire (PSQ; Wurtele, 1990), Fox, McMorrow, Storey, and Rogers (1984), and Gerdtz (2003). Ideas and items compiled in the focus groups with German experts will enhance the measurement. The board game will be simple and colourful, as needed by our specific target group.

(2) Prevention knowledge: Verbal report. Participants will be presented vignettes (short video clips) that display the beginning of a sexual abuse situation. Participants will be asked how they would react if this were to occur to them. Participant answers will be measured by established formats used by Khemka (2000), Khemka et al. (2005; Decision Making Video Scale) and Tang and Lee (1999; also ‘What If’ Situation Test by Wurtele, 1990). Answers will be scored using the scale developed by Miltenberger and colleagues (Egemo-Helm et al., 2007; Lumley, Miltenberger, Long, Rapp, & Roberts, 1998). One point will be recorded for each of the following behaviours, with four points being the maximum score (from Lumley et al., 1998): (a) does not agree to engage in, or begin to comply with, the requested behaviour (appraisal); (b) says ‘no’ or otherwise verbally refuses (refusal); (c) leaves the situation or tells the offender to leave (escape); and (d) reports the incident to a staff person (report). In Miltenberger’s studies, if the individual agreed to engage in or began to comply with the requested behaviour, she received a score of 0. Rules of scoring will be discussed for plausibility within focus groups.

(3) Prevention behaviour: Role Play. Participants will take part in role plays with a similar content and identical methodology as used in the training. The trainer will present the inappropriate request shown in the video clip, which, to our knowledge, will be the first time this particular method is used. The participant will be instructed to respond to the lure as if it were a real situation. In contrast to the verbal report, the participant must exercise her (behavioural) response. Responses will be rated on the same scale adapted by Miltenberger and colleagues (Lumley et al., 1998) for verbal reports.

(4) Prevention behaviour: In Situ Test. To ensure a valid evaluation, in situ probes will be used to operationalize the outcome variable ‘sexual abuse prevention skills’. In situ probe assessments evaluate participants’ behaviour in a
Before 1998, researchers relied on indirect methods of assessment, such as verbal descriptions of behaviour in As-If-Situations (Lumley & Miltenberger, 1997). While using role plays as a more behavioural measure proved promising (Tang & Lee, 1999), it cannot be inferred that subjects with ID generalize the content learned in role plays to everyday life. According to Lumley and Miltenberger (1997) and Miltenberger et al. (1999), there was no empirical evidence that knowledge learned in role plays will be transferred to actual abusive situations. So-called ‘in situ probes’ in their design came closer to real-life situations and thus were more likely to evoke ecologically valid responses (Lumley et al., 1998). For this reason, in situ probes were introduced to the evaluation of sexual abuse prevention programmes by Miltenberger and his team (Lumley & Miltenberger, 1997) and have been used so far on four studies on adults (Egemo-Helm et al., 2007; Lumley et al., 1998; Miltenberger et al., 1999). A more recent study by Kim (2016) proved in situ tests to be feasible for children as well. For ethical reasons, in situ probes follow a strict protocol (as demanded by Egemo-Helm et al., 2007; Kim, 2016; Lumley et al., 1998): the probes must address parents’ concerns (Kim, 2016) but should still be able to generate ecologically valid data. Strict rules will be established for all in situ probes in this study. There will never be any physical contact between the confederate and the participant. The tone of voice will always be friendly; never will the confederate use his tone of voice to build up pressure (e.g., through yelling). A staff person from the school or a trainer will be nearby but out of sight. All in situ probes (as well as all other measurements) will be videotaped for both the participant’s safety and the confederate’s protection. Standard operating procedures (SOPs) will be established for different stages of the in situ probes. The following example describes the endpoint of measurement: ‘If the participant agrees to the requested behaviour, the confederate will interrupt immediately for an alleged reason or will make an excuse to leave. If the participant asks the confederate to leave, he does so immediately. If the participant does not react at all, the confederate leaves after a specified amount of time (15 seconds, as recommended by Watson et al. [1992]).’ The number of in situ probes will be limited to one in situ probe per point of measurement; measurement errors should be minimized by the number of participants and a randomization of the sequence of situations presented across measurements per participant. Such errors include but are not limited to the offender’s appeal to the participant (see Efran, 1974) or a varying degree of commotion elicited by the request (e.g., giving a kiss vs. undressing).

By employing this multiple-probe-across-participants design, our study will be the first to use a large sample receiving a training compared to a control group receiving a sham intervention. Moreover, the amount of data will allow for analyses of associations between prevention knowledge and prevention behaviour. All tests will be videotaped. Videotaping the assessments will allow for examining the adherence to the measurement protocols and ensuring the compliance with ethical standards. It will enable us to gain data from different blinded raters (see Brunnekreef, van Uden, van Moorsel, & Kooihoos, 2005), thus minimizing rating bias (see Chodan et al., 2014).

2.4. Development of the intervention

The training will be developed in a 4-step process (see Fig. 2). As a result of a literature review, a first version of training manual will be discussed by German experts. The second version of the programme will then be piloted for feasibility.

None of the studies reviewed mentioned a feasibility study or a pilot study of any kind (Chodan et al., 2014). The feasibility study will include 15 participants who are equally distributed to the three sites (five subjects at each institution). Adaptations will be made according to the results of the feasibility study. During the final period, specially trained staff will implement the programme at the schools of the study subjects. The group trainings will consist of 10 group sessions, each lasting 90 minutes. This amount of time will give the trainer opportunities to adjust to the participants’ pace and incorporate breaks. Sessions of this length will be easy to embed in the German school setting. Groups will consist of 4–8 girls and one trainer. A group will be defined by a minimum of two participants.

2.5. The intervention programme Emma untouchable

The training’s rationale will be based mainly on behavioural therapeutic exercises and also contain psychoeducational elements. Many concepts will be presented first in a rather cognitive yet still play-like manner and will be exercised later in a behavioural way, e.g., during role plays. Sequences of behavioural exercises and reflection will alternate so that participants can observe the concept at work on themselves or others. Observations and descriptions of other
A puppet called Emma will ‘assist’ the trainer in teaching the concepts (see Caputo, 1993) serving as an ‘advanced coping model’. So-called mastery models exclusively demonstrate the successful mastery of a requirement, with objectives leading to this goal left unquestioned. Coping models demonstrate a coping behaviour that expressly highlights the difficulties that prevent the successful handling of a particular requirement. While studies on adults without ID showed a distinct advantage of coping modelling over mastery modelling (e.g., Cunningham, Davis, Bremner, Dunn, & Rzasa, 1993), the efficacy of coping modelling in children has been criticized (Ginther & Roberts, 1983). The Emma puppet will thus be conceptualized as a mixture of a coping model and a mastery model, allowing the girls to imitate the model and to develop their own strategies and insights. Our review of the literature led to a manual conceptualized for 10 sessions. Sessions will be similar in structure and will try to build preventive skills in an incremental fashion. The sessions are described below:

- **Session 1:** ‘Introduction and getting to know each other’. In this session, the trainer will introduce herself and Emma and outline the aims of the training. Rules will be announced and negotiated. The three repeating exercises that frame each session will be introduced (one introductory activity that opens each session and two conclusive activities that close each session). Self-assertiveness will be introduced.

- **Session 2:** ‘Body language and emotions’. Bodily expression of emotions and the deliberate use of strong (confident) body language will be experienced and reflected upon.

- **Session 3:** ‘Basic self-defence in situations of anger and fear in everyday life’. In this session, confident body language and speaking one’s mind will be exercised in default and in personal situations.

- **Session 4:** ‘Situations of anger and fear in everyday life and getting help’. Aspects of confident body language will be repeated. Seeking and getting help from peers and adults will be introduced for everyday-life situations.

- **Session 5:** ‘Naming private parts, reflecting on touch, and learning about bodily autonomy’. The children will learn the terms for private parts and will reflect on touch. They will learn why a touch is perceived as pleasant or unpleasant. In a drawing exercise, participants will

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**Fig. 2. The development of the intervention programme.**
conceptualize two sources for emotions – who touches them and where they are touched. They will learn about their right of bodily integrity and autonomy.

- Session 6: ‘Feelings and the connection between feelings and touch’. Building on topics from previous sessions, a connection will be established between emotions and touch. By paying attention to one’s negative feelings, the child will be able to recognize signals of potential sexual molestation or a crossing of physical boundaries.

- Session 7: ‘Feelings and boundaries and learning about prevention skills’. The association between negative emotions and molestation established in Session 6 will be deepened by focusing on how to address infringements. The use of confident body language should be re-activated, now augmented with the prevention skills described by Lumley et al. (1998): (1) not engaging the proposed sexually abusive situation (non-verbal refusal), (2) verbally refusing the proposition, (3) ending the situation by either leaving or telling the offender to leave, and (4) reporting the situation to a trusted adult. Situations will be preset by video clips specifically designed for the project that depict potentially abusive situations with a girl serving as a role model. Participants will practice prevention skills in role plays by re-enacting scenes from the video clips.

- Session 8: ‘Prevention skills applied in potentially harmful situations, with a special focus on bribes and acute danger’. Prevention skills learned in Session 7 will be practiced in more default role plays, focusing on offender strategies of luring children into abusive situations by bribing them. In a second set of exercises, participants will be taught strategies for dangerous situations.

- Session 9: ‘Prevention skills applied in potentially harmful situations, with a special focus on offenders’ strategies of concealment’. Prevention skills learned in Sessions 7 and 8 will be practiced in more default role plays, focusing on the offenders’ strategy of secrecy. Participants will learn to discriminate between pleasant and harmful secrets by drawing on what has been learned about paying attention to one’s feelings. Simple rules will be specified to identify potentially harmful secrets and how to address them.

- Session 10: ‘Prevention skills applied in potentially harmful situations, with a special focus on disclosure; concluding the training’. Prevention skills learned in Sessions 7–9 will be practiced in more default role plays. The importance of reporting to a trusted adult will be emphasized. Children will identify confident persons to contact in case of abuse. The training will be concluded with multiple rounds of repetition. During the farewell exercise, participants will receive training materials and prompts that have been used and collected throughout the training. The session will end with the ritualized closing exercise.

Role plays require all parties to understand and remember who is playing which role, involving complex cognitive skills to differentiate between the immediate situation and the pretend situation. If girls with ID are unaware of why they are carrying out such behaviour, little will be learned (Lee, McGee, & Ungar, 2001). Thus, children with ID engaging in role plays on sexual abuse prevention require aids. In their work with adults, Khemka (2000, 2005) and Bollman and Davis (2009) presented vignettes in short video clips that either included a scene overlaid with a verbal narrative or scenarios acted out by confederates. Video clips have a low degree of abstractness and are of a highly stimulative nature; their applicability and benefits are rated as excellent, while their effectiveness remains to be shown. During the feasibility period, the requirements for children with ID to understand the role play concept will be determined.

This study will use video clips in a sexual abuse prevention programme with children, visualizing when and why relevant skills can be applied. The training will combine video clips and modelling the target behaviour in the role plays, guiding participants in how to utilize the newly learned skills. A great variety of vignettes will depict various sexual abuse lures and situation-inappropriate touches and inappropriate embodiments of relationships. The content of the vignettes will be derived from focus groups and from the literature (Egemo-Helm et al., 2007). Each vignette should take approximately 90 seconds to watch.

The training programme will be manualized and made semi-open to the public and should enable skilled workers from the health care system to conduct the training. The control group receives a sham intervention that teaches the participants road safety and self-assertive behaviour in various situations (e.g., using public transportation or dangerous traffic situations). Detailed information can be obtained from the first author.

2.6. Acceptance and adverse effects

At the last point of measurement, parents will be asked to complete a questionnaire on social validity, comprising the overall acceptability of the programme and of the study, the rate of any change observed in their child’s behaviour, and possible...
harm occurring after participation in the study (see Fig. 1). The social validity measures will be informed by the work of Lumley et al. (1998) and Egemo-Helm et al. (2007). In their schooling prior to the study’s implementation, trainers will be sensitized to adverse events, especially when (1) trainers observe unusual behaviour, (2) the child discloses abuse during the course of the study, and/or (3) caretakers observe unusual behaviour and/or disclose child abuse. All these events and the steps that follow will be documented carefully. If the trainer observes unusual behaviour (or a caretaker mentions it), the trainer will first seek to speak with the child. Together, they will determine whom to involve as a trusted adult, as is also the case when the child discloses child sexual abuse (CSA) or other forms of abuse. The trainer will help to initiate the contact, e.g., with the parents or with a counselling centre.

Since prevalence rates suggest that up to one-third of children with ID have been victims of CSA, it is anticipated that some participants have experienced CSA prior to the study or may even experience CSA during the course of the study. These children are deliberately not excluded from the study as a group, but participation will be carefully considered on a case-by-case basis to avoid retraumatization. Thus, if a parent discloses an incident of CSA, the parent will be advised by the trainer regarding what possible steps to take and, together, they will determine how to protect the child during the course of the study (e.g., excluding the child from the in situ assessments).

2.7. Ethical considerations
The study will comply with the Declaration of Helsinki in its latest revision. The seventh revision emphasizes the dissemination of research results, including negative outcomes and risks and/or injuries to the participants. This demand applies particularly to this study, in which various measures of safety must be developed. All procedures will be in accordance with the ethics committee of the University of Rostock as well as the federal state government of Bavaria. The subjects’ parents and/or guardians will be fully informed about the study goals, their right to withdraw at any time, procedures, analyses, and data reporting prior to participation. Parents and guardians will provide written consent for their children and clients to participate in the study and for videos to be taken, pseudonymized, and rated. Measures for data protection (pseudonymization and securing data with passwords or locks) will be developed. The intervention will be offered to the girls in the control group after their data are gathered completely (see Fig. 1, so-called ‘ethical training’).

Safety during measurements will also be ensured in various ways. For all measurements, ethical standard operation procedures will be developed and will be easy to prove by inspecting the videos. These will include guidelines for the actors and for the preparation of locations, such as comparable means of escape for the participants and the setup of the video camera. During all assessments, a trusted adult will wait outside the test room to offer immediate emotional support in case a participant needs it. Standard ethical operation procedures will be developed for the training programme itself. Trainers should be enabled to react appropriately if a participant discloses an experience of sexual abuse during the training. Trainers will receive supervision throughout the implementation of the programme and the study and will be required to videotape their sessions.

2.8. Measures against bias
To overcome a weakness of previous studies, the video recordings of all assessments will be rated by three blind raters. Effects will be estimated by the statistical means of all judgments.

Several measures will be adopted to provide for sufficient quality assurance with regard to the group trainings. Trainers will receive extensive schooling. Each session and evaluation will be recorded on video. Video recordings will be checked at random for trainers’ adherence to the manual. Supervision will be offered throughout the training process.

Different steps will be taken to avoid situational effects during measurement. In situ scenarios will be randomly drawn from a pool of four scenarios at t1, requiring a new situation for every point of measurement. In this way, we will try to promote generalization through varying the offender strategy. Potential biases (i.e., faces of actors functioning as prompts, effects due to affection) should be reduced by using different confederates at each measurement. For the verbal report and role-play assessments, two different situations will be tested at each point of measurement, drawing randomly from a pool of situations that depict offenders varying in age, relationship to the child, and sex. Focus groups with German experts in combination with findings from existing literature should ensure that common scenarios will be used. Situations for verbal reports and role plays will correspond because the video clip used for the verbal reports should help the participant to assume her role by imitation and to understand the role of the trainer playing the offender.

2.9. Data analysis
Data will be analysed using MANOVAs with all four measures of prevention skills (knowledge, verbal reports, role plays, and in situ probes) as dependent variables and modelling IQ, speech ability, behaviour
problems (SumScore CBCL), and stage of sexual maturity as covariates. The time range will encompass three points of measurement. Effects of the booster session will be calculated as group comparisons of the dependent variables.

The scale used by Miltenberger’s study group (Egemo-Helm et al., 2007; Lumley et al., 1998; Miltenberger et al., 1999) will be used for comparative analysis. For our analyses, the scale will be altered to allow weighing the possible behavioural reactions to a sexual abuse lure (appraisal, refusal, escape, and report). While not beginning to comply with the requested behaviour (appraisal) is a good start, it does not yet clarify that the child does not want to engage in the behaviour (the child might not have fully understood the request or might not know how to start carrying out the behaviour), thus giving the offender an opportunity to carry on with the lure. Thus, this behaviour is rated as 1 point. A refusal, on the other hand, sends a clear signal to the offender that the behaviour is unwanted and is thus rated as 2 points. However, this move still leaves the offender and the child in the same place (literally and figuratively) and does not end the at-risk situation. Ending the situation (escape) by either leaving it or telling the offender to leave is thus rated as 3 points. To ensure that the likelihood of a future at-risk situation is reduced, the child needs to report the incident to a trusted adult. Since reporting the incident will – hopefully – lead to long-term protection, it is rated as 4 points. Thus, a participant can achieve a maximum sum score of 10 points by displaying all four behaviours.

3. Discussion

The study proposed here will be the first to attempt to bring prevention skills to a large sample of a highly vulnerable group: girls with ID. The idea to train potential victims of sexual abuse should of course not be understood as a way to make or keep these girls responsible for events that happen to them. Responsibility for CSA always falls on offenders, perhaps a relative or an insufficient safeguard. However, learning about early warning signs, dangerous situations, and strategies to end these situations might enable girls with ID to participate in the world in more ways, to defend their right to physical autonomy, and to be heard. To achieve this, not only careful interventions but also sophisticated evaluations are needed. The study proposed here addresses many of the shortcomings of earlier works. For the first time, a programme for girls with ID is evaluated not only with a sufficient sample but also on different dimensions of prevention skills, avoiding as many biases as possible. The study introduced here nevertheless has some risks and limitations, which should be discussed here.

As is the case with studies on minors, consent to participate will be acquired by the children’s parents/guardians, which carries a risk of parents opting to not participate in the study when they themselves are perpetrators or aware of intrafamily abuse, attempting to avoid its disclosure. Thus, effects of secondary prevention or of (re)traumatization cannot be estimated in this study. Some hints should nevertheless be analysed. First, we will count the numbers of families asked to participate but not enrolled in the study. Second, data will be analysed in an intention-to-treat manner in which every drop-out during the study not attributable to reasons outside the study will be coded as a ‘harm’ due to participation.

In situ probes of prevention behaviour are regarded as state of the art (Egemo-Helm et al., 2007; Kim, 2016) but still suffer from limitations. Actors posing as offenders are unknown to the children, whereas, in real life, over 90% of offenders and their victims know each other well (Balogh et al., 2001; Mansell et al., 1992). While this gap cannot be closed due to ethical considerations, video clips used in this programme and its evaluation capture examples of more realistic situations between relatives, close acquaintances, and persons of authority. The situational context of abuse, however, could not be introduced into the study design for several reasons. First, a second group factor with several categories (e.g., violent/nonviolent and known/unknown offenders) would have extended the model beyond the scope of this project, which is funded by the German government. Second, in no way would realistic test situations have been possible for in situ probes. For these reasons, we attempt to eliminate this factor by randomizing situations throughout groups and points of measurement. A final validation would require demonstrating that the prevention programme lowers the actual rate of participants becoming victims of sexual abuse in life after training. Participants and their caregivers could be issued a questionnaire when the former reach young adulthood.

This programme focuses on girls only. While girls comprise the biggest group of potential victims, at least in institutions (Euser et al., 2016), the authors are aware that much more needs to be done in the field. Boys seem to be equally endangered in foster families (Euser et al., 2016) and tend to transition more easily from victim to perpetrator.

Last, this programme focuses directly on behaviour change. In child sexual abuse, however, the vulnerability of the victim is only one factor that makes an offense more likely. Even if the training enhances the prevention skills of girls with ID, it could never substitute a careful prevention policy for those children.

Author details

All authors contributed substantially to the conception of the study, drafting the paper, and giving final approval for
publication. They agreed to be accountable for all aspects of the work described here.

**Availability of data and study material**

The datasets analysed during the current study will be available from the corresponding author on request.

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No potential conflict of interest was reported by the authors.

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