

BMJ Open Prevention of child mental health problems in Southeastern Europe: a multicentre sequential study to adapt, optimise and test the parenting programme 'Parenting for Lifelong Health for Young Children', protocol for stage 1, the feasibility study

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ABSTRACT

Introduction Families in low-income and middle-income countries (LMICs) face multiple challenges (eg, poverty and adverse childhood experiences) that increase the risk for child mental health problems, while the context may provide them with few resources. Existing prevention-oriented parenting programmes have been shown to be effective in reducing child behaviour problems and associated risk factors. This project has the overall goal of adapting, implementing and testing a parenting intervention in three Southeastern European LMIC and uses the Multiphase Optimisation Strategy and dimensions of the Reach, Effectiveness, Adoption, Implementation and Maintenance framework. It is implemented over three phases: (1) preparation, (2) optimisation and (3) evaluation. The preparation phase, the subject of this paper, involves the adaptation and feasibility piloting of the parenting programme.

Methods and analysis This protocol describes the assessment of an evidence-informed indicated prevention programme for families with children aged 2–9 years (Parenting for Lifelong Health for Young Children) for implementation in FYR of Macedonia, Republic of Moldova and Romania. In this phase, officials, experts, parents and practitioners are interviewed to explore their views of suitability and needs for further adaptation. In addition, a small pre–post pilot study will test the feasibility of the programme and its implementation as well as the evaluation measures in the three countries with 40 families per country site (n=120). Quantitative data analysis will comprise a psychometric analysis of measures, testing pre–post differences using ANCOVA, χ^2 tests and regression analysis. For qualitative data analysis, a thematic approach within an experiential framework will be applied.

Strengths and limitations of this study

- The overall project uses an innovative design: it is informed by implementation science and applies dimensions of the Reach, Effectiveness, Adoption, Implementation and Maintenance and the Multiphase Optimisation Strategy framework to develop an optimised intervention that takes into consideration contextual resource constraints and challenges.
- The qualitative and quantitative results from phase 1 will provide detailed information about programme acceptability and adoption, as well as potential implementation facilitators and barriers.
- The qualitative data are intended to help understand the reasons behind potential implementation problems and how these could be addressed.
- Potential adverse events that occur during the study will be assessed to enhance knowledge about potential harms caused by the intervention.
- Preliminary pre–post effects of the parent programme on parent and child outcomes will be assessed in three countries.

Ethics and dissemination The ethics review board of the Alpen-Adria University Klagenfurt and ethical review boards in the three LMIC sites have approved the study.

Trial registration number NCT03552250.

INTRODUCTION

There have been increasing calls for reduction of the global burden of mental diseases (eg, Ordóñez and Collins¹). As psychological health problems usually arise early and

persist during life,² the treatment of emotional and behavioural problems in children is a primary pathway to increase global mental health.^{1 3 4} In order to reduce the duration of untreated mental health problems, prevention programmes for child mental disorders have been widely recommended.¹ Alongside other prevention programmes, parenting trainings have shown to be effective and cost-effective in both the short-term and long-term regarding parent and child emotional and behavioural outcomes with small to moderate effect sizes in high-income countries.^{5 6} These interventions usually aim to enhance parenting practices and the parent–child relationship through teaching and practising new skills to increase positive parent–child interactions and emotional communication, as well as to use positive discipline strategies and parental consistency.⁷ However, only a small percentage of these randomised controlled trials (RCTs) have been conducted in low-income and middle-income countries (LMICs), although most of the world's population of children and adolescents live there (almost 90%).³ Consequently, there have been increasing demands for high-quality studies testing the evidence for existing child mental health interventions in LMIC.⁸

Identifying effective interventions for the prevention of child behaviour problems in LMIC is extremely important, because the families in these countries are often faced with a number of challenges that are associated with a high risk for child mental health problems, such as family and youth violence, parental stress and/or alcohol misuse.^{3 9 10} Existing evidence for child mental health interventions implemented in LMIC is promising: Several reviews^{11–13} have demonstrated positive short-term and long-term effects of parenting programmes on parental practices, child–parent interaction and child behaviour problems across studies and countries. However, the quality of studies was mixed and the range of the effect sizes across studies was wide. Thus, high-quality studies testing prevention programmes for child mental health in LMIC are urgently needed.³

As in other LMIC, families in the Southeastern European countries, Republic of Moldova (low-middle income country), FYR of Macedonia and Romania (upper-middle-income countries), usually have few family and child support programmes available¹⁴ despite facing multiple challenges. The prevalence of psychological risk factors for child mental health problems, such as child maltreatment, parental alcohol misuse, family violence or children left behind because of migration^{10 15–17} and socioeconomic difficulties (eg, social injustice and poverty),¹⁸ is high. An RCT in Bosnia-Herzegovina demonstrated promising results from a parenting programme: the training for mothers had positive effects on maternal problems and child emotional and behavioural problems for some (but not all) of the outcome measures.¹⁹ However, mothers received a parenting intervention and additional free basic healthcare. Thus, the individual effect of the parenting intervention can only be estimated.

RESEARCH AIM

Aim of the overall project

The primary aim of the overall project—(Prevention of Child Mental Health Problems in Southeastern Europe, which has the acronym RISE)—is to apply rigorous research methods to optimise a parenting programme so that it meets the specific needs and constraints of families in three LMIC in Southeastern Europe (FYR of Macedonia, Republic of Moldova and Romania). The design is informed by two research methodologies: the Multi-phase Optimisation Strategy (MOST)²⁰ and the Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) framework.²¹

The MOST framework is derived from engineering and human resource principles and aims at developing an optimised multicomponent behavioural, biobehavioural or biomedical intervention within specific contextual constraints (eg, limited resources) in an ongoing improvement process. Thus, it targets the development of an economic, efficient, effective and scalable intervention while making the most efficient use of available resources. The MOST framework comprises three distinct phases: preparation, optimisation and evaluation. The preparation phase includes clarification of the intervention conceptual model, identifying candidate intervention components or component levels to be tested in the subsequent phase, pilot testing and revision of the intervention. Also, key constraints (eg, staff time, parent drop-out/retention) are identified to inform optimisation criteria that operationalise the final product of the optimisation process. In the optimisation phase, intervention components or component levels will be tested in a factorial experiment to identify the most efficacious, cost-effective and scalable combination of components in the three countries. In the evaluation phase, the new optimised intervention package will then be tested in a multisite RCT across the three countries.²⁰

A second objective of this project is to apply dimensions of the RE-AIM model^{21 22} to carefully plan, monitor and evaluate the implementation process and to assess barriers to implementation, integration with existing service delivery systems and scale-ups at each study phase to facilitate sustainability and real-world applicability. There is a clear need to examine contextual factors that influence the adaptation and implementation of such interventions in LMIC.^{3 8} Therefore, it is essential to identify and apply an implementation model that increases reach, efficacy, adoption, implementation and sustainability of the optimised programme in addition to evaluating its effectiveness.^{21 23} RE-AIM aims to enhance the successful translation from research into practice of an intervention by evaluating five dimensions: Reach (number and representativeness of participants), Efficacy (effect on primary and broader outcomes), Adoption (proportion and representativeness of professionals and organisations that deliver the intervention), Implementation (quality of programme delivery in practice/staff adherence) and Maintenance (extent to which the

intervention is delivered over time and to which the participants continue to use the new skills). The RISE conceptual model combines the ideas of the RE-AIM with the MOST frameworks in order to maximise the probability that the optimised programme will be implemented sustainably and at large scale in practice in the three countries.

Aim of the present feasibility study (phase 1: preparation phase)

This study aims to test the feasibility of the intervention, the implementation and evaluation procedures including retention, recruitment and assessments. This allows for changes and modifications prior to further testing. Although limited by small sample size due to its pilot study design, the feasibility study can also examine preliminary effects of the programme on reducing child behaviour problems and associated risk factors.²⁴ The following research questions will be tested:

1. What is the feasibility of delivery of the adapted version of Parenting for Lifelong Health (PLH) for Young Children and are the evaluation methods appropriate and feasible? What are the procedures that need to be adapted or changed for the later study phases?
2. Among families participating in the programme, are there pre-post improvements on child and parental mental health and behaviour?
3. Are the measures and indicators for the evaluation of phases 2 and 3 feasible (including potential moderators and RE-AIM items)?

METHODS AND ANALYSIS

Design

The present study is a single-arm multisite pre-post pilot trial; no allocation to conditions and no blinding is conducted. It is part of a larger sequential prevention study with the intervention and procedures for the later study phases being adapted based on the results of this pilot study. We used the Standard Protocol Items: Recommendations for Interventional Trials checklist when writing our report.²⁵

Setting and location

One institution per country, guided by a local principal investigator (PI), will conduct the recruitment and implementation on site. In FYR Macedonia, the Institute for Marriage, Family and Systemic Practice—ALTER-NATIVA conducts research and education in systemic family psychotherapy and systemic practice in Skopje. In Moldova, the implementation will be conducted by the Health for Youth Association in Chisinau, a non-governmental organisation (NGO) that aims to promote access to services related to general, mental and sexual reproductive health of adolescents and young people. In Romania, the Health Psychology Research Group of the Babes-Bolyai University will guide the implementation of the study in the city of Cluj-Napoca.

The country research teams will obtain referrals from local partner organisations (eg, NGOs, governmental organisations, family and social services, child mental health services, schools and kindergartens), invitations to community groups and leaders (eg, for Roma communities) as well as 'word-of-mouth' referrals in the community to recruit participating families. Moreover, information about the study will be disseminated via leaflets and Facebook websites in all targeted communities. Families will be able to contact the research team for up to 12 hours daily via phone. Each of the three country sites will select communities likely to enable the recruitment of high-risk families (eg, from low income and/or minorities, such as Roma communities). To facilitate participation, both the assessments and the parenting groups will be delivered at a time and venue that is suitable for the parents (eg, community and health centres, schools, assessments at parents' homes).

Intervention

The parenting programme to be implemented was developed as part of the PLH, an initiative led by Unicef, WHO and partner academic universities, with the aim to develop and test a suite of affordable parenting programmes specifically to meet the need in LMIC for low-cost interventions. One programme from this suite is the subject for this study: PLH for Young Children, a 12-session group-based programme for parents of children from 2 to 9 years, that was originally developed and tested in South Africa. The programme has shown promising results for increasing positive parenting and reducing harsh parenting and other risks for maltreatment in two RCTs in South Africa, as well as for reducing child behaviour problems in the Philippines.^{26–29}

PLH for Young Children is based on social learning theory principles and includes the following general content/topics: (1) Spending one-on-one time with your child; (2) Using words to describe actions; (3) Talking about feelings; (4) Using praise and rewards to reinforce positive behaviours; (5) Giving positive, specific and realistic instructions; (6) Establishing consistent household rules and routines; (7) Redirecting negative behaviours to positive behaviours; (8) Ignoring negative attention seeking and demanding behaviours; (9) Using consequences to support compliance; (10) Using cool-down as a consequence for aggressive behaviour; (11) Avoiding and resolving conflicts in the family and (12) Reflection, celebration and moving on. Core activities during the sessions include group discussions, illustrated vignettes, practising parenting skills in role-plays in the group, collaborative problem solving, implementing parenting skills at home and providing feedback on the experiences of parents at home.²⁹

Participants

Parents

Primary caregivers with at least one child aged between 2 and 9 years will be recruited to participate in the

programme. For testing the training and programme procedures in each country comprehensively, we plan to train several facilitators at each country site and to conduct four parenting groups per country (10 families per group). Thus, the target sample size is 120 families ($n=40$ per country). This sample size is sufficient to test the feasibility of the training ($n=24$ facilitators, 8 per country), implementation of the programme, recruitment and the assessment processes.

Additional inclusion criteria for participating adults are: (1) age 18 years or older, (2) live in the same household as the target child for at least four nights a week and will continue to do so during the course of the study, (3) reports elevated levels of targeted child behaviour problems, (4) agrees to participate in the PLH for Young Children programme, (5) provides informed consent to participate in the study. Exclusion criteria for parents include any adult that (1) exhibits severe mental health problems or acute mental disabilities or (2) who has been referred to child protection services due to child abuse.

Facilitators

Staff in the field of family and child services (eg, psychologists, social workers, teachers) will be recruited to deliver the programme. Inclusion criteria comprise: (1) age 18 or older, (2) prior participation in a PLH for Young Children facilitator training workshop, (3) agreement to deliver the entire PLH programme according to protocol, (4) willingness to be videotaped to assess skills and intervention fidelity during the sessions and (5) consent to participate in the full study. Strategies to ensure adherence by facilitators include an intensive training workshop, a programme manual containing working material for parents, fidelity checklists and regular coaching sessions.

Stakeholders and parenting experts

The following stakeholders will be recruited to support programme implementation and adaptation and to help with knowledge translation, contextual adaptation and adherence to the local culture with an eye to eventual scale-up in the three countries (12–20 per country): (1) practitioners who are front-line local social and health service providers who provide services to families with children aged 2–9 years, (2) experts who are key professionals involved in child and family health and welfare services (eg, academics, psychologists, paediatricians and social workers) and (3) district, provincial and national level government and policy-makers from the Ministries of Public Health and Social Welfare/Development.

Additionally, professionals who have expertise in the field of parenting interventions will be recruited in order to provide feedback on the adaptation and implementation of the PLH programme (six experts per country). Stakeholders and parenting expert need to be age 18 or older and provide informed consent to study participation.

Procedures

The study will take place from April 2018 to December 2018 (anticipated completion date for the postassessment: October 2018, and for the qualitative data assessment and analysis: December 2018). In order to train local facilitators in conducting the PLH for Young Children, the programme materials will be translated into Romanian, Albanian and Macedonian, with surface local contextual adaptation (eg, of programme content and its complexity of stories, names and gender roles). Facilitators will be trained by one of the developers of PLH for Young Children in each country. Trained data assessors will obtain informed consent, screen parents individually for eligibility and complete preassessment. Postassessments will be conducted following programme completion.

Quantitative data collection (parents)

Quantitative data collection will employ computer-assisted self-interviewing ('CASI') method with electronic-tablet technology to administer consent forms and questionnaires. Trained data assessors will read out questions, and assist participants to key responses into the tablet. If any participants are unable or uncomfortable to use the tablets, paper-and-pen questionnaires will be available. In addition, the study will use audio-CASI to administer sensitive items on the questionnaires (eg, regarding child maltreatment) to increase willingness to report stigmatising experiences.³⁰ Participants will have the option to either read or use the audio function using earphones when responding to questions.

Qualitative data collection

Postintervention, programme acceptability and participation will be explored using qualitative in-depth interviews with intervention participants ($n=9-15$) and focus group discussions with the facilitators ($n=8$) in each country. Interviews and focus group discussions will examine participant-reported change in parenting practices and child behaviour at home; acceptability and appropriateness of programme materials, delivery, and key programme components. Also, existing barriers to, and facilitation of, participation during sessions and engagement in home practice and other activities will be assessed. Implementation barriers (eg, staff turnover, scheduling) and facilitators (eg, perceived trust from family towards facilitator) for the staff will be identified. Qualitative in-depth interviews with stakeholders and parenting expert groups will be conducted to gather information relating to their perceptions of the design and the adaptation of the intervention in their country. Additionally, stakeholders will provide information about potential barriers to study participation by parents and the programme adoption by facilitators as well as potential strategies to overcome these barriers.

Compensation of participants

Parents will receive a food voucher or hygiene products (worth approximately €5 per participant) after each set of assessments is completed and refreshments will be provided during data collection. Parents will receive a

snack and a transportation allowance at each programme session, and a certificate of completion for participation in the programme. If a parent does not miss more than one group session, he/she will receive an award, worth approximately €3. Lunch and breaks with refreshments will be available during the interviews with experts, facilitators and stakeholders. Reimbursement for local transport will also be provided for the expert working groups.

Data monitoring

The RISE research practices will be monitored in three ways: via a data and safety monitoring board (DSMB), an ethics advisor (EA) and a data protection officer (DPO). The DSMB and the EA are independent of the research team and the content of the project.

Potential harms to participants

This is a minimal risk study for the stakeholders and parenting experts. With regard to the parents, it is not anticipated that the research is likely to cause serious distress, given that the selected intervention has been successfully evaluated several times before. Nonetheless, efforts will be made to ensure that parents are comfortable during the process. For participants who still need an intervention after completion of the parent training or are identified as needing another service during the programme, referrals to local services will be provided (there are no restrictions regarding concomitant care). The following procedures for the monitoring of adverse events, aiming at identifying potential unexpected negative intervention side effects, will be pilot tested in this study phase: (1) project staff will report any adverse event of which they become aware to the country PI, (2) the country PIs will examine the adverse event report, decide on further actions (eg, referral to local agencies, report to DSMB, institutional review board (IRB) and local child protection services, if necessary) and inform the overall project coordinator, (3) the DSMB and the IRB will review the potential harms to participants and decide whether the study needs to be terminated. Also, the PIs will stop the study if participants suffer an unanticipated risk or if it is not feasible to complete the study within ethical guidelines.

Measures

All measures including the implementation outcomes, child and parent mental health and behaviour questionnaires, and additional measures for the evaluation of phases 2 and 3 are described in detail (including psychometric properties) in the online supplementary file.

ANALYTICAL STRATEGY AND DATA MANAGEMENT

Data analysis

Quantitative data

When appropriate, missingness will be handled using multiple imputation at the item level to account for missing data.³¹ If this imputation is not possible or relevant, for instance, due to the small sample size and variable distribution patterns, alternative methods for

handling missingness will be considered (eg, full information maximum likelihood estimation).

Psychometric analyses will be conducted to evaluate the performance of each scale in each language and across the pilot sample to inform revisions necessary for phases 2 and 3. Descriptive statistics and distributions at the item and scale level will be examined and compared with existing data in other samples when available (eg, scores on the Alcohol Use Disorders Identification Test or Child Behaviour Checklist, for a description of measures, see the online supplementary file). Internal consistency, convergent, concurrent and discriminant validity will be examined to inform decisions about phase 2 measures. Structural validity via exploratory factor analysis will be performed on the total sample for scales or subscales with 12 items or fewer (given the sample size of 120).

To examine the pre-post change on primary and secondary outcomes, baseline and post-test scores will be compared using analysis of covariance (ANCOVA), incorporating relevant continuous covariates or χ^2 tests for categorical variables. ANCOVA and regression analyses will be used to examine whether implementation factors (Reach, Efficacy, Implementation) relate to mean scores on primary and secondary outcomes.

Qualitative data

Data analysis will be conducted in each country by two coders. The research team will use a thematic approach within an experiential framework to analyse the data from the individual interviews and focus groups.³² An initial coding framework and protocol will be developed. The codes will then be grouped into themes based on the respondents' feedback on PLH for Young Children core themes, programme structure and schedule, programme logistics, and issues as well as implementation barriers affecting the potential for programme scale-up.

Data management

All non-anonymised non-electronic data including signed consent forms, transcripts, interviews and quantitative paper questionnaires will be stored in a locked filing cabinet at each country site. Video recordings of group sessions will be stored on a password-protected hard drive in a locked cabinet. Data from tablets will be anonymised, and directly uploaded and saved onto a secure university server with limited access. Access to these data will be controlled and require authorisation from the research teams for further use. A comprehensive data management plan is available on request.

Patient and public involvement

Parents were not involved in the development of the research question, the selection of outcome measures or the study design of phase 1. Parents were partly involved in the recruitment of participants (eg, word-of-mouth referrals, parent associations). Additionally, local stakeholders and service institutions supported the recruitment of families and provided feedback on the study.

Local practitioners and researchers provided feedback on measures prior to the study. One of the primary aims of this study phase is to collect information from parents on the assessment and intervention procedures to inform phases 2 and 3. Thus, in the next study phases 2 and 3, parents' priorities, experiences and preferences resulting from phase 1 will be considered for adaptation of the research questions, the study design and the outcome measures. Based on the quantitative and qualitative results of phase 1, the programme components to test, the assessment and implementation procedures will be adapted. We plan to disseminate the study results to participants and public via the project website (<http://www.rise-plh.eu>).

ETHICS AND DISSEMINATION

Consent to participate

All participants (parents, experts, facilitators, stakeholders) will provide written informed consent prior to any study procedures (forms available on request).

Protocol amendments

Interim results for each study phase will be discussed within the RISE research team and changes to the protocol will be made, if necessary. Any subsequent modifications to this protocol for phase 1 (V.02; issue date: 13 September 2018) need to be approved by all PIs and will be submitted to the IRB and the DSMB for consideration and approval.

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Contributors NH, HMF and JML have prepared the grant proposal and developed the design and the conception of the study. AB, XF, GL and MR are PIs on the RISE study and contributed to the conception of the study implementation and development including data acquisition. JML, JH, CLW and FG are developers of the PLH programme, PIs on the project and contributed expertise to the study design and the implementation of the PLH program, as well as to the writing of the respective protocol parts. IF and NH conceptualised the data monitoring procedures, were responsible for the coordination of the work and prepared the manuscript draft, HMF and EJ are key contributors to the design of the assessments, data analysis and management and drafted the respective sections. XF is responsible for the design and analysis of the cost-effectiveness analysis. MEW contributed to

the design, particularly with regard to the collection of qualitative data. All authors have revised the manuscript critically for important intellectual content, have approved the final version of the manuscript to be published and have agreed to be accountable for all aspects of the work.

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Competing interests AB, XF, HMF, EJ, GL, MR, and MEW have nothing to disclose. IF reports personal fees from Hamburg University, and other institutions offering education for psychotherapy in Germany outside the submitted work; IF is a certified trainer of the Triple P program. FG is a co-developer of PLH for Young Children, which is licensed under a Creative Commons 4.0 Non-commercial No Derivatives license, and one of the co-founders of the Parenting for Lifelong Health initiative. FG has participated (and is participating) in a number of research studies involving the program, as an investigator, and the University of Oxford receives research funding for these. LML reports personal fees from Clowns Without Borders South Africa, grants from University of Oxford, and other from Parenting for Lifelong Health, outside the submitted work; NH reports grants and non-financial support from Technische Universität Braunschweig, during the conduct of the study; personal fees from other academic institutions offering continued education for psychotherapy education in Germany, outside the submitted work; and NH serves as an international advisory board member for the Triple P program. JH is a co-developer of PLH for Young Children, which is licensed under a Creative Commons 4.0 Non-commercial No Derivatives license, and one of the co-founders of the Parenting for Lifelong Health initiative. She is the director of the Children's Early Intervention Trust, a non-profit institution responsible for the dissemination of the program in Europe. She receives occasional fees for providing training and supervision to facilitators and coaches. JH has participated (and is participating) in a number of research studies involving the program, as an investigator, and Bangor University receives research funding for these. JH contributed to the initial trial in South Africa, the trial in the Philippines and led the evaluation of the program in a pre-post trial in Montenegro. CLW reports grants from World Childhood Foundation, and grants from UBS Optimus Foundation via the Philippine Ambulatory Pediatric Association, outside the submitted work; CLW is a co-developer of PLH for Young Children, which is licensed under a Creative Commons 4.0 Non-commercial No Derivatives license, and one of the co-founders of the Parenting for Lifelong Health initiative. CLW has participated (and is participating) in a number of research studies involving the program, as an investigator, and the University of Cape Town receives research funding for these. She receives no direct personal income from this work.

Patient consent for publication Not required.

Ethics approval The study has been approved by the Human Research Ethics Board of the Alpen-Adria University Klagenfurt (Board Approval Number: 2018–21) and the local IRBs in each country site: Human Research Ethics Commission at the School of Medicine – St. Cyril and Methodius University Skopje, Macedonia (number 03-1460/11); Ethics Committee of Research of 'Nicolae Testemitanu' State University of Medicine and Pharmacy of the Republic of Moldova, Chişinău, Moldova (nr. 43 la nr. 56) and the Ethical Committee of Babes-Bolyai University, Cluj-Napoca, Romania (number 3533/05.03.2018).

Provenance and peer review Not commissioned; peer reviewed for ethical and funding approval prior to submission.

Data sharing statement Data will be shared among the RISE research team. It is planned to make some anonymized datasets available to the public and other researchers via an open-access repository following the FAIR (Findable, Accessible, Interoperable, Reusable) principles. The research team will ensure that results will be published in open access peer-reviewed journals.

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