BMJ Open

Assessing the efficacy of a brief universal family skills programme on child behaviour and family functioning in Gilgit-Baltistan, Pakistan: protocol for a feasibility randomised controlled trial of the Strong Families programme

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To cite: El-Khani A, Asif M, Shahzad S, *et al*. Assessing the efficacy of a brief universal family skills programme on child behaviour and family functioning in Gilgit-Baltistan, Pakistan: protocol for a feasibility randomised controlled trial of the Strong Families programme. *BMJ Open* 2024;**14**:e081557. doi:10.1136/bmjopen-2023-081557

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (https://doi.org/10.1136/bmjopen-2023-081557).

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Received 24 November 2023
Accepted 13 May 2024

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ABSTRACT

Purpose The global burden of mental health difficulties among children underscores the importance of early prevention. This study aims to assess the efficacy, feasibility and acceptability of the Strong Families programme in enhancing child behaviour and family functioning in low-resource settings in Gilgit-Baltistan, Pakistan.

Methods and analysis This is a two-arm, multisite feasibility randomised controlled trial with an embedded process evaluation in three districts of Gilgit-Baltistan, namely Gilgit, Hunza and Skardu. 90 families living in these challenged settings, comprising a female primary caregiver aged 18 or above, and at least one child aged 8–15 years, will participate. Participants will be randomly assigned to either receive the Strong Families programme or to the waitlist group. Strong Families is a 7-hour family skills group intervention programme attended by children and their primary caregivers over 3 weeks. The waitlist group will be offered the intervention after their outcome assessment. Three raters will conduct blind assessments at baseline, 2 and 6 weeks postintervention. The primary outcome measures include the feasibility of Strong Families, as determined by families' recruitment and attendance rates, and programme completeness (mean number of sessions attended, attrition rates). The secondary outcomes include assessment of child behaviour, parenting practices, parental adjustment and child resilience. Purposefully selected participants, including up to five caregivers from each site, researchers and facilitators delivering the intervention, will be interviewed. Descriptive statistics will be used to analyse primary and secondary outcomes. The process evaluation will be conducted in terms of programme context, reach, fidelity, dose delivered and received, implementation, and recruitment.

Ethics and dissemination This study has been approved by the UNODC Drug Prevention and Health Branch in the Headquarters office of Vienna and the National Bioethics Committee of Pakistan. Findings will be disseminated through publication in reputable journals, newsletters and presentations at conferences.

Trial registration number NCT05933850.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study uses a randomised controlled trial design, a robust methodology for assessing intervention effectiveness.
⇒ Integrates both quantitative and qualitative methods embedded within a process evaluation, to enhance insights into programme context, fidelity and implementation.
⇒ Various key feasibility indicators, including recruitment rate, retention and adherence, will be thoroughly examined.
⇒ The inclusion of three districts in Gilgit-Baltistan will enhance the study's external validity and generalisability.
⇒ Follow-up assessments at 2 and 6 weeks may restrict the ability to capture longer-term intervention effects; however, this could be addressed as part of a future definitive trial.

INTRODUCTION

Mental health challenges pose a significant global burden, underscoring the urgency of preventive efforts, particularly from early childhood.[1] Individuals living in challenging settings, especially in rural and low-resource areas, are vulnerable to enduring mental health difficulties, psychosocial challenges and emotional distress. This leads to vulnerabilities such as alcohol and drug abuse, low self-esteem, health problems, academic

struggles, self-harm and even suicide.[2] The mental well-being of children is closely linked with that of their parents or caregivers, as parents facing mental health challenges may encounter difficulties in providing optimal care for their children.[3] Moreover, the mental health of caregivers is associated with long-term emotional, cognitive and behavioural problems in children.[4] The presence of parental mental health challenges, particularly depression, can independently and interactively predict emotional and behavioural challenges in children.[5] Providing care for children can be demanding, especially when parents lack adequate resources and support, leading to adverse effects on parental mental health.[6]

Gilgit-Baltistan, a newly created province in Pakistan, is a remote and geographically isolated region. The region's challenging terrain hinders frequent interaction with other areas of the country.[7] With an estimated population of 2 million, Gilgit-Baltistan's hilly landscape and limited road infrastructure often leave communities isolated due to emergencies like landslides, damaged bridges or congestion.[8] Adolescents in this region have shown concerning rates of alcohol use, and previous studies have highlighted the presence of mental health problems such as anxiety and depressive disorders, particularly affecting women.[9–11] Disturbingly, suicide rates in Gilgit-Baltistan may surpass those in other parts of the country, with risk factors including educational failure, psychological disorders, domestic issues, the shift from joint to nuclear families and poverty.[12 13]

Recognising the significance of strengthening family relationships to promote positive parenting knowledge and skills, various protective factors, such as effective communication, trust, problem-solving abilities and conflict resolution, can enhance caregiver–child bonding and attachment.[2 14–16] In this context, the 'Strong Families' programme, an evidence-based intervention, has been specifically designed for families living in the context of stressful, fragile and challenging humanitarian settings. Strong Families programme aims to empower families by acknowledging their strengths and sharing strategies to overcome challenges, fostering family well-being and mental health for children aged 8–15 years. The programme has been successfully implemented and evaluated in a neighbouring country, Afghanistan.[17 18] It has since been assessed on families living in a similar context in other countries, such as Afghan refugees in reception centres in Serbia,[19] Iranian and Afghan families in Iran.[14]

As the programme is designed to be delivered by lay facilitators with no previous expertise, this has been conducted by representatives of local civil society organisations, staff of schools and primary healthcare centres, and social workers with the majority having no previous experience in facilitating prevention programmes. The Strong Families programme has demonstrated alignment with its expected short-term outcomes, showcasing enhancements in parenting practices, child mental health, improved family management skills, positive shifts in children's behaviour and increased capabilities for caregivers to cope with stress.[14 17 19] The programme has proven to be effective and feasible, particularly in resource-constrained settings.[19] These noteworthy findings warrant further investigation and additional studies.

With this background and given the scarcity of psychosocial and medical facilities as well as limited research in Gilgit-Baltistan,[7 10] we have designed a study to test Strong Families to influence family well-being by improving child behaviour, parent–child relationship and family functioning in this region. Close consultation with the programme developers will ensure a tailored approach. The current study aims to address the knowledge gap and contribute valuable evidence in enhancing child well-being and family dynamics among families in the unique context of Gilgit-Baltistan, Pakistan.

AIMS

The current study aims to evaluate the feasibility, acceptability and short-term efficacy of Strong Families for families with a female caregiver and their children aged between 8 and 15 years in improving family skills outcomes and caregiver and child mental health, as reported by caregivers in Gilgit-Baltistan.

METHODS

Study design

This is a multisite, two-arm feasibility randomised controlled trial (RCT) with families randomly allocated to either the intervention group, where they will receive group sessions of the Strong Families programme (with 8–12 families per group), or the control group, which will place families on a waiting list who will receive the Strong Families training sessions after completion of outcome assessments. To ensure the study's success and refine methodologies, a small pilot study involving 10 families will be conducted before the main RCT. This pilot will help researchers become familiar with the evaluation tools used and ensure facilitators are proficient in delivering the Strong Families programme. The data from this pilot will not be analysed as part of the study's findings. The trial will include an embedded process evaluation to monitor and assess the implementation of Strong Families and its fidelity across the different sites.

Study setting

The study will be conducted from June 2024 to December 2025 in three districts including; Gilgit, Hunza and Skardu in Gilgit-Baltistan, Pakistan. Strong Families will be delivered in schools where families will have easy access and where there is the availability of two classrooms for the programme to run. Gilgit-Baltistan is a region in northern Pakistan, bordered by Afghanistan to the northwest, China to the northeast, and Azad Jammu and Kashmir to the south. The estimated population of Gilgit-Baltistan is around 2.5 million.[20] Gilgit-Baltistan is undoubtedly a

challenging setting. The region faces poverty and unemployment. There is limited access to education and financial resources influencing the quality of life for people living there. The effects of climate change, unpredictable weather patterns and the lack of adequate infrastructure, including roads, electricity and healthcare facilities pose significant environmental and socioeconomic challenges for the overall development and well-being of the population.[21 22]

Participants

The study will include female caregivers aged 18 or above, primarily mothers but also potentially aunts or grandmothers, along with at least one child aged 8–15 years under their care. The sampling approach will be opportunistic, employing a 'universal' method, where facilitators will enrol families from the general population rather than targeting specific risk groups. While cultural norms in Pakistan allow for the participation of only one gender in the group, we have carefully considered the dynamics of caregiving roles. Our understanding, based on a previous study in Afghanistan[17] and reinforced by our experience, indicates a predominant caregiving role among females. Adhering to the cultural context and prevailing societal roles, the study will include only female caregivers and their children (of any gender). Eligible participants should be fluent in Urdu, capable of comprehending it and able to provide informed consent. Each female caregiver will be welcomed to attend with a maximum of two children aged 8–15 for inclusion. The exclusion criteria will be the following: (1) families who have previously engaged in another family skills training programme within the past 6 months; (2) the caregiver and child living separately and (3) unlikely to be available for the duration of the whole study and outcome assessments (eg, temporary residence).

Recruitment

Female caregivers will be invited via a self-referral process to attend an information session either held by locally trained researchers in community settings or schools. Families who express interest in participating or receive invitations from the research team, along with their eligible children, will receive an information sheet and the research team's contact information. They will have a 4-day window to initiate contact if they wish to participate in the study. If they express interest, a researcher will reach out to obtain their informed consent. The study team will maintain regular communication with participants during the study duration, ensuring their engagement and retention, and keeping them updated on the study's progress. These interactions may take the form of brief phone calls at regular intervals.

Randomisation

Families will be randomised to Strong Families (intervention group) or the waitlist group by an independent trial statistician. Families will be allocated to study arms with equal probability (1:1). The randomisation process will be implemented independently at each of the three sites to ensure balance in sample size and participant allocation to intervention and control groups. On randomisation, the trial statistician will provide the project manager with the randomisation details of families. Subsequently, the project manager will communicate the allocation details to the facilitators. Following randomisation, each family will receive a unique study identification number and be informed of their assigned groups within a week. It is not possible to blind the facilitators and participants of group allocations; however, the baseline and outcome assessments will be administered by the research assistant blind to randomisation status. Participants will be encouraged not to reveal group allocations to researchers conducting assessments. Records will be maintained for any instances of unblinding. The trial statistician will be blinded to group allocations. The statistician will conduct regular quality checks throughout the trial. Once all data have been entered, the preliminary analysis of the data will be carried out prior to unblinding.

Intervention

Strong Families[14 19 23] is a family skills programme designed to provide evidence-informed prevention support. Its primary focus is to enhance family skills and empower caregivers to become better parents, fostering positive age-specific and age-appropriate family functioning and interactions. By strengthening the family structure and dynamics, the programme aims to prevent drug use, violence and other negative social consequences in children. Strong Families programme is a 3-week group intervention attended by both children and their primary caregivers, lasting a total of 7 hours (seven sessions) over a period of 3 weeks. In the first week, caregivers gather for a 1-hour caregiver session. In the subsequent weeks, the same caregivers and their children meet again separately in parallel sessions for the first 1 hour, after which all caregivers and children convene in one room for a joint family session lasting 1 hour.

Strong Families programme has been translated into the Urdu language. Pakistan has significant ethnic diversity, encompassing various cultures and subcultures. The linguistic landscape remains rich and varied as people here speak numerous languages. Though Urdu holds the status of the national language and is widely spoken and understood.[24] New data from Iran[14] indicate cross-cultural effectiveness in different cultures of the same community. Cultural adaptation of Strong Families to the Pakistan context was achieved through an expert group including a master trainer, a bilingual health expert, mental health professionals and the programme developer, that is, UNODC. The expert group was involved in an iterative process to achieve a mutual acceptance level of abstraction as well as obtaining an identical meaning of concepts having different cultural expressions including revising the language (where needed) without altering the logical

Table 1 The structure of the Strong Families programme

Week 1	Caregiver presession		
Week 2	Caregiver session 1	Child session 1	Family session 1
Week 3	Caregiver session 2	Child session 2	Family session 2

framework of the programme. These adaptations were made for the purpose of training and implementation.

The structure of the Strong Families programme is summarised in table 1.

Facilitators trained in Strong Families will administer the intervention on a weekly basis over a period of 3 weeks, with regular supervision from trainers.

Sample size

We aim to recruit 90 families (N=45 in intervention, N=45 in the waitlist group) in total (30 families from each of the three study sites). The audit of sample sizes for pilot and feasibility RCTs has revealed a median sample size per arm of 30 across various studies,[25] thus, requiring a sample size of N=30 per group for the current study. Based on the recruitment rates in the previous trials[17 19] in similar contexts, we are not expecting a large dropout rate in this study. However, we have taken a possible attrition rate into account and aim to include 50% more participants making a sample size of 45 per group.

Outcomes

Primary outcomes: We will record feasibility indicators as primary outcomes in terms of families' recruitment (how many families consent for study participation), the number of sessions attended and programme completeness, that is, the mean number of assessments completed, and attrition rates from the study. The recruitment rate will be determined based on the number of families consenting to participate by the total number of eligible families approached. Comprehensive records on reasons for exclusion and refusal to participate will be documented. Participant engagement will be closely monitored, including the total number of sessions attended, completion of follow-up assessments, and tracking drop-out and withdrawal rates. Continuous documentation at both process and content levels throughout the study will be maintained. The need for a full definitive trial will be determined if, at the study's end, the following criteria are met recruitment >50% to a substantial representation of the intended sample size, retention >70% to maintain a considerable size for comparison at the end of the study (Lyles *et al*; Amico, 2009), session attendance >60% and assessment completion >70% to ensure a substantial exposure to the intervention (at least participants attend more than half of the sessions) and meaningful engagement to conclude, attrition remains <30% and to maintain the reliability of the study's findings, as exceeding this threshold indicates significant flaws and necessitates caution in interpreting the results (Amico, 2009). Acceptability of the intervention will be assessed based on participants' satisfaction, attendance and attrition rates) and participants' feedback. Fidelity tools after each session with the families will be completed.

The study encompasses a comprehensive process evaluation that aims to evaluate the implementation, contextual factors, participants' satisfaction and the impact of the Strong Families. The secondary outcomes include various assessments: caregivers will complete a 25-item behavioural screening using the Strengths and Difficulties Questionnaire (SDQ)[26] and respond to the 30-item Parenting and Family Adjustment Scale[27] to gauge parenting practices and parental adjustment. Likewise, children will complete the SDQ[26] and the revised Child and Youth Resilience Measure[28] to identify available individual, relational, communal and cultural resources that might contribute to their resilience. To ensure consistency, the same primary caregiver attending all Strong Families sessions will administer the assessments at all time points and rate the child with whom they have the most challenges. The primary caregiver must answer the questions with the same child in mind at every time point. There will be a total of three paper-pencil assessments: at baseline (T0) (1 week before Strong Families programme delivery), 2 weeks (T1) and 6 weeks (T2) postintervention delivery. We will record the demographic characteristics of participants at baseline.

Study procedure

After the consent process, families will be invited to attend a meeting in which they will complete baseline assessments (both child and caregivers will complete individual questionnaires), assisted by a researcher. Two weeks after the last session Strong Families, all caregivers and children (also those from the waitlist group in the RCT) will be invited to complete the same questionnaires they completed at baseline assessment. Six weeks after the last session, all caregivers and children will be invited to the final assessment, to complete the same questionnaires again. Figure 1 illustrates the study procedure and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) diagram is also given (see figure 2). A completed SPIRIT checklist is given as online supplemental additional file 1.

Statistical analysis

The SPSS (Version 27) will be used to analyse study data. Appropriate descriptive statistics and graphical summaries will be used to present both baseline and outcome assessment data. We will follow Consolidated Standards of Reporting Trials guidelines for reporting and analysis. Statistical analysis will be undertaken by a researcher with relevant expertise. Intervention and waitlist groups will be assigned to the respective group and participants will be analysed according to the intention to treat. Ideally, all participants will be followed up. In case of loss of follow-up or not all questions being answered, a non-responder analysis will be

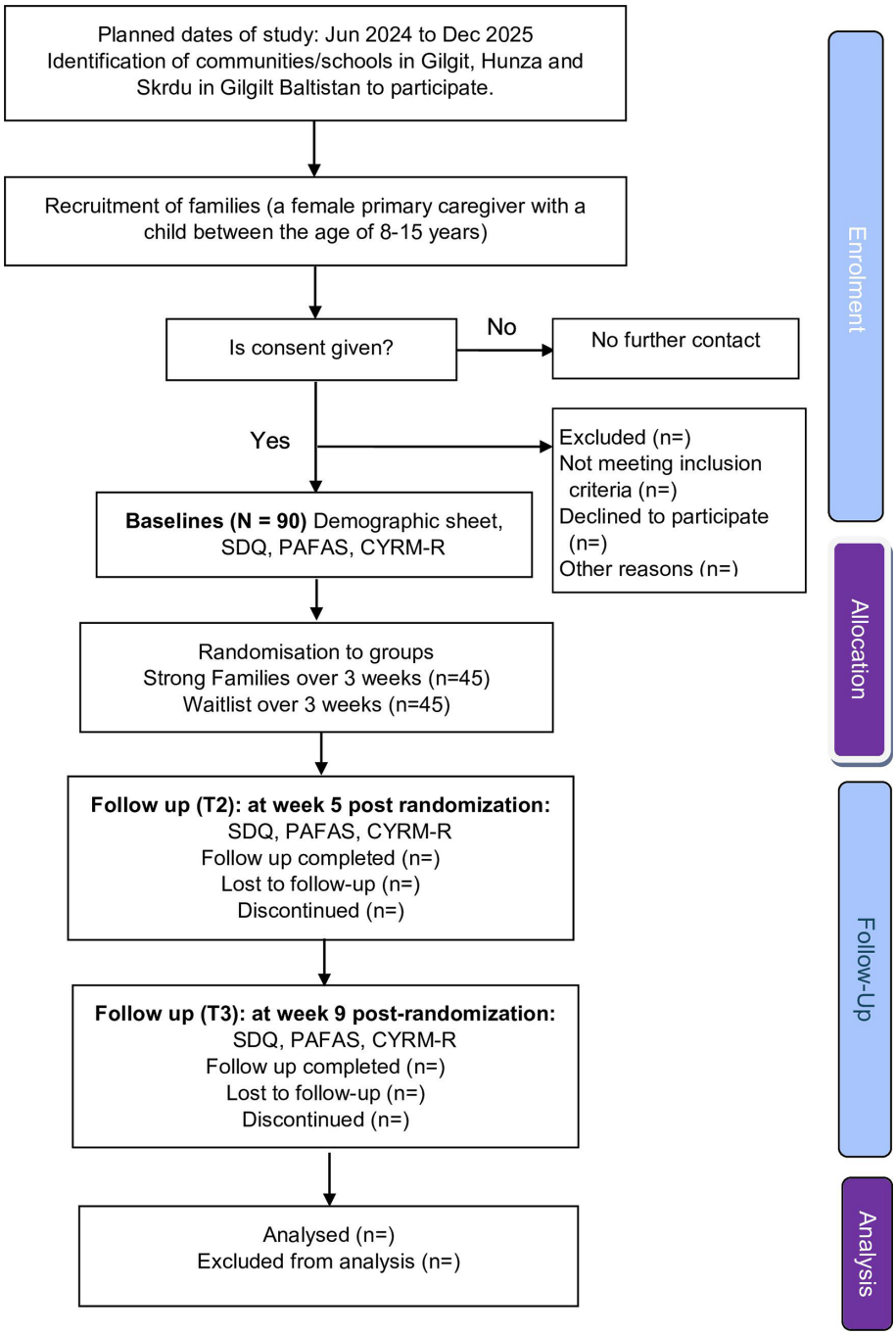

Figure 1 Flow diagram describing the study procedure and timelines. CYRM-R, revised Child and Youth Resilience Measure; PAFAS, Parenting and Family Adjustment Scale; SDQ, Strengths and Difficulties Questionnaire.

performed and those who did not attend follow-up will be compared with the remaining. Possible between-group differences will be assessed using t-test and χ^2 tests. Within-group comparisons at different time points will be measured using repeated measures analysis of variance. Stratified analyses comparing participants with high scores to low scorers at baseline will be performed. Any other relevant analyses depend on the nature of the data. Any missing data will be handled through modelling on the assumption that it is missing at random. Logistic regression will be used to test this assumption and to calculate the probability of providing complete outcome data with baseline variables as predictors. These analyses will be used to create inverse probability sampling weights for subsequent analyses on outcome. Effect sizes, along with 95% CIs, will be determined to conduct power calculations for a larger trial. The p value will be reported and 0.05 will be considered as significant. We will consider small sample size adjustments, if applicable. A complete statistical analysis plan will be written before the database lock and subsequently will be discussed and approved by the trial steering committee (TSC).

	STUDY PERIOD						
	Enrolment	Allocation	Trial Period				
TIMEPOINT	$-T_0$	0	*Baseline (T0)*	W_1	W_2	W_3 (T1)	M_6 (T2)
ENROLMENT:							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
INTERVENTIONS:							
Strong Families Programme				←	—	→	
Waitlist				←	—	→	
ASSESSMENTS:							
Demographic information sheet			X				
SDQ			X			X	X
PAFAS			X			X	X
CYRM-R			X			X	X

Schedule of enrolment, interventions and assessments.

Figure 2 Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) diagram. CYRM-R, revised Child and Youth Resilience Measure; PAFAS, Parenting and Family Adjustment Scale; SDQ, Strengths and Difficulties Questionnaire.

Process evaluation

We will purposefully select up to five caregivers from each study site (N=15 caregivers) for semistructured interviews to explore their opinions on the programme and identify participation barriers or facilitators. The interviews will be conducted by trained qualitative researchers who are proficient in the local languages spoken by the caregivers. We will use a semistructured approach with interview guides to cover key investigation areas, ensuring we don't miss any unexpected issues. Selection will consider age, clinical and recovery scores for diverse perspectives. The interviews will explore cultural acceptability, programme usefulness, engagement barriers and facilitators, adherence factors, and recruitment experiences. We will also interview the research team, including facilitators and researchers. To evaluate the programme, we will follow the Linnan and Steckler framework,[29] assessing fidelity (programme alignment with the plan), contextual factors (programme delivery setting), programme reach (proportion of approached vs attending participants) and delivered/received session counts. The evaluation will also gauge Implementation (a composite score of reach, dose and fidelity) and recruitment methods. These comprehensive measures will provide a nuanced understanding of programme implementation and its impact.

Qualitative analysis

A thematic analysis approach[30 31] will be employed, focusing on identifying major themes and subthemes that arise from the collected data. To preserve the participants' nuanced perspectives, transcriptions in the local language will be initially completed by native speakers and afterwards translated into English by bilingual experts who have a good understanding of the cultural context. Two independent experienced qualitative researchers will conduct initial coding, subsequently comparing and reaching a consensus on an appropriate coding strategy. These codes will be aggregated across datasets, leading to the identification of overarching themes and subthemes. Regular discussions among researchers will refine these themes to closely align with participants' perspectives, minimising redundant ideas. To enhance the credibility and trustworthiness of the findings, the researchers will receive supervision and guidance from qualitative

research experts. Ongoing discussions and reviews with senior researchers will ensure the congruence of data with the final analysis and minimise bias.[32] Ultimately, key themes and interpretations that emerge from this process will be presented.

ETHICS AND DISSEMINATION

The study has been reviewed and approved by the UNODC Drug Prevention and Health Branch in the Headquarters (HQ) office of Vienna, the national United Nations Office on Drug and Crime (UNODC) project office in Pakistan and the National Bioethics Committee (NBC) of Pakistan reference number (4-87/NBC-861/22/418). All procedures performed in studies involving human participants will be in accordance with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. In case of any protocol amendments, this will be communicated to NBC and other relevant authorities. Furthermore, we will ensure the trial registration is kept up to date, and the revised protocol will be shared with the research team and study investigators.

Consent

Consent will be obtained through caregivers completing a consent form before completing the baseline assessments. Participants will be provided with a verbal explanation of the evaluation method at the first meeting along with a written information sheet. This will include explaining the study purpose, participants' rights to refuse participation or to withdraw their participation without any consequences, confidentiality and privacy. Written consent from interested participants will be obtained. Those who are unable to read and write will be offered the option of audio recorded verbal consent, in the presence of an independent representative or family member/carer chosen by the participant. We will seek assent from participating children.

Data management

Data will comply with the Data Protection Act (1998). Each participant will receive a unique study ID for anonymity. Identifiable information will be securely stored and accessible only to authorised personnel. Interviews, with consent, will be audio recorded using encrypted digital devices. Notes from observations will be transcribed promptly and stored with transcriptions. Personal details will be removed from transcripts and notes. Encrypted devices (at least 256-bit encryption) will be securely stored. Interview recordings will be transcribed on a password-protected computer, ensuring anonymity. Once transcriptions are verified, recordings will be destroyed in the presence of a senior qualitative researcher.

Data collected will be confidential and accessible to the trial team only. Whenever possible, anonymised data will be used. Digital data will be stored separately from personal details. Non-digital data will be retained in a study-specific locked cabinet for at least 5 years after project completion while digital data will be stored using Epidata software. Caregiver and child names will be collected for identification but will only be used during the intervention and data collection phase, with no electronic storage of identifying data.

Data monitoring and oversight

The research team will convene to assess the trial's progress and make decisions concerning operational matters linked to the study monthly. The responsibility of coordinating activities across study sites will rest with the trial manager. Additionally, an impartially led TSC and a data safety and monitoring board (DSMB) will provide oversight at all stages of the trial. The TSC and DSMB will operate independently from the trial management team. The TSC will convene every 6 months and will seek guidance from the chair as necessary between scheduled meetings. The DSMB will continuously evaluate both the data and ethical aspects of the trial, offering recommendations to the TSC regarding potential alterations to the trial's implementation and whether any ethical or safety considerations warrant discontinuation of the trial.

Adverse events and harm reporting

The planned study is not anticipated to result in any negative outcomes, and there is no foreseen harm associated with participation. However, facilitators will be vigilant to red flags that would be raised during the delivery of Strong Families such as sensitive topics that need to be addressed on an individual basis rather than discussed in group settings. Facilitators will keep a list of services available for referral purposes (legal/mental health/sanitation/social assistance or other services). This list of services could be updated with the evolving experience of facilitators with the main needs of families during the implementation. As this is a preliminary study to assess feasibility, no alterations will be made in the sessions. However, a thorough evaluation process will be conducted to enhance the intervention for a potential future comprehensive trial. If any participants experience any possible distress, they will be advised that they do not need to answer any questions they are not comfortable with and they may withdraw from the study. Research staff will receive training and supervision focused on identifying and managing distress in participants and making referrals if necessary. Following the study's completion, participants in the waitlist control group will also have access to the intervention. Any adverse events that occur during the trial will be documented, and any such event will be reported to the principal investigator within 24 hours of its occurrence. Participants can access any routine care treatment during participation.

Patient and public involvement and engagement

Patient and public involvement and engagement (PPIE) will be carefully incorporated into this study to ensure a holistic and patient-centred approach. We will establish a dedicated advisory group comprising individuals from

diverse backgrounds, including caregivers with young children and representatives from the broader community. This group will actively participate in shaping the research process, data analysis and interpretation. Regular meetings and open forums will provide platforms for the advisory group to share their perspectives, experiences and suggestions, allowing their insights to influence key decisions. We will also seek their feedback on study materials, questionnaires and interview guides to ensure they resonate with the target audience. Moreover, we will encourage participants to voice their preferences and concerns regarding the project and engage them to create lay summaries of study findings in local languages and in study dissemination. Through such a concerted PPIE approach, we aspire to cultivate a research environment that respects and integrates the invaluable input of patients and the public, ultimately enhancing the impact and relevance of our study outcomes.

Dissemination plan

The dissemination and impact activities of the project will include peer-reviewed academic publications in high-impact journals, and presentations at national and international conferences. Presenting findings at conferences will allow for direct engagement with experts and researchers, fostering valuable discussions and potential collaborations. We will organise public talks and workshops to engage with the broader community, including caregivers, community leaders, teachers and the general public. The research findings will be adapted into lay summaries with accessible language and interactive formats, encouraging meaningful dialogue and raising awareness. A dedicated webpage for the study will be created to share lay summaries, infographics and other resources such as newsletters in regional languages. The study will also use social media platforms to engage a wider audience.

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Acknowledgements We acknowledge the support of the United Nations Office of Drugs and Crime (UNODC) team, particularly Karin Haar, Mara Urlicic, Ali Yassine, Giulia Martinelli and Esra Köymen Irmak to provide support in manual formatting, Strong Families training, and management of online training portal. We would also like to acknowledge the support of the Ishrat Husain Pakistan Institute of Living and Learning (PILL) team in manual translation, and cultural adaptation particularly, Muhammad Awais, Sana Farooq, Dr Munazza Obaid and Muzaffar Ali.

Contributors The study was conceptualised by AE-K, MA and M-CVH as a collaborative effort. AE-K, MA and WM contributed to the study design and methodology. MA mainly drafted the manuscript and MSB supported the drafting. SS, ABK, M-CVH, NH, WM, NC, ZZ, RM, IBC, AT and NuZR provided substantial input through critical review and contributed to manuscript refinement and editing. All authors reviewed and approved the final draft of the manuscript.

Funding This study is primarily funded by the Pakistan Institute of Living and Learning (Ref# PILL202429). UNODC has provided in-kind support by providing the Strong Families Manual and training to the research staff in Pakistan. Strong Families was developed by UNODC thanks to the support of the US-INL (Bureau of International Narcotics and Law Enforcement Affairs). The implementation of Strong Families globally through UNODC has been made with the support of the governments of Sweden, France, Japan, Slovenia and US-INL. None of the donors had any role in the writing of this communication.

Disclaimer The views expressed here are those of the authors and not necessarily those of UNODC and PILL.

Competing interests IBC, NC and NH have disclosed engagements encompassing presentations and consultancy roles with Eli Lilly, Bristol Myers Squibb, Lundbeck, AstraZeneca and Janssen Pharmaceuticals. These interactions led to reimbursements for them or their respective employing institutions. NH and IBC have held positions as trustees at the PILL in the past. NH has also held roles as a trustee for organisations including Manchester Global Foundation, Lancashire Mind and Abaseen Foundation, UK. Additionally, NH is an NIHR senior investigator and serves as the Director of Research and Innovation at Mersey Care NHS Foundation Trust. Importantly, none of the aforementioned companies maintains any financial stake in this research.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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