ISRCTN66706005 https://doi.org/10.1186/ISRCTN66706005

Testing a programme to support the emotional and behavioural wellbeing of children aged 5–10 years in Albania

Submission date	Recruitment status	[X] Prospectively registered
09/11/2026	Not yet recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/11/2026	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/11/2026	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Public

Contact name
Mrs Ilva Vjero

Contact details
Rruga Skënderbej, Nd. 6, H. 2, Ap. 17–18
Tirana
Albania
1000
+355 (0)692122989
ilva.vjero@tdh.org

Type(s)
Scientific

Contact name
Dr Sarah Skeen

Contact details
Education Building, Francie van Zijl Drive, Tygerberg
Cape Town
South Africa
7505

+27 (0)21 938 9043
skeens@who.int

Type(s)
Principal investigator

Contact name
Dr Felicity Brown

Contact details
United Nations Ave, Gigiri | Nairobi, Kenya
(working remotely in France, GMT+1)
Paris
France
75001
+254 (0)207621234
febrown@unicef.org

Type(s)
Principal investigator

Contact name
Mrs Ilva Vjero

Contact details
Rruga Skënderbej, Nd. 6, H. 2, Ap. 17–18
Tirana
Albania
1000
+355 (0)692122989
ilva.vjero@tdh.org

Additional identifiers

Study information

Scientific Title
A feasibility randomized controlled trial of the BLOOM intervention for children aged 5–10 years in Albania

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 29/09/2026, Research Ethics - Faculty of Social Sciences, University of Tirana (Bulevardi "Gjergj Fishta", Tirana, 1000, Albania; +355 (0)4 222 8402; fshs.ut.info@unitir.edu.al), ref: Not yet assigned

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Emotional and behavioural difficulties in children aged 5–10 years, including difficulties with emotional regulation, managing behaviour, relationships and interactions with caregivers, and psychosocial wellbeing

Interventions
Eligible children and their parents or primary caregivers will be enrolled in the study following screening, eligibility assessment and informed consent. 60-80 families will be recruited from selected community-based services in Tirana and Kukës, Albania. A sample size of minimum 60 participants was determined to be sufficient to answer the feasibility trial research questions. Based on the identification, recruitment, and screening process, we expect at least 60 families to be enrolled, but this number may increase to maximum of 80 families taking part in BLOOM, depending on eligibility rates and baseline completion rates.

Participants will be individually randomised within each municipality (Tirana and Kukës) using a 1: 1 allocation ratio. The randomisation sequence will be computer-generated by the University of Tirana, with separate allocation sequences for each municipality. Randomisation will take place after completion of baseline assessments. The research team will securely maintain the allocation information and communicate group assignments to the intervention providers. Providers cannot be blinded to group allocation as they are responsible for delivering the intervention. Data collectors (outcome assessors) will remain blinded to participants' group allocation throughout outcome data collection, wherever possible. Any accidental unblinding will be documented.

1. Intervention group (BLOOM):
Families will receive the BLOOM intervention, a structured psychosocial programme designed to support children's emotional and behavioural wellbeing and strengthen positive parenting and caregiver-child interactions. The intervention will be delivered by trained non-specialist providers to children aged 5–10 years and their parents or primary caregivers. It will consist of nine sessions, each lasting approximately 60 minutes, delivered over a period of approximately

2–3 months. Sessions will cover topics including parenting skills, emotional regulation, positive behaviour support, problem-solving and strengthening caregiver-child relationships. The programme will also include referrals to specialised services when needed.

2. Control group (care as usual):
Families allocated to the control group will continue to receive the usual services and support available through community-based services and other relevant local providers. They will not receive the BLOOM intervention during the initial comparison period. Following completion of the post-intervention assessment, families in this group will also be offered the BLOOM programme.

Data will be collected at baseline and endline. Child and caregiver outcomes will be assessed using standardised questionnaires, including the Paediatric Symptom Checklist (PSC-35), Kiddy-KINDL, the Behaviour and Feelings Survey, the Brief Parenting Scale and the Kessler Psychological Distress Scale (K6). Assessments will be conducted by trained assessors who will be masked to group allocation.

The study will assess the feasibility and acceptability of delivering the BLOOM intervention in the Albanian context, as well as changes in children's emotional and behavioural difficulties, psychosocial wellbeing and parenting-related outcomes.

Intervention Type
Behavioural

Primary outcome(s)
1. Emotional and behavioural difficulties measured using the caregiver-reported Pediatric Symptom Checklist (PSC-35) total score at 12 weeks after baseline assessment (endline)

Key secondary outcome(s)

Completion date
30/09/2027

Eligibility

Key inclusion criteria
1. Children aged 5–10 years at the time of enrolment
2. Children identified as experiencing emotional and/or behavioural difficulties through the adapted Reach Now tool
3. Children who meet the study's eligibility criteria based on the screening and assessment procedures
4. Children living in the selected study areas in Tirana or Kukës
5. Children whose parent or primary caregiver is willing and able to participate in the BLOOM programme and related study assessments
6. A parent or legal guardian who is willing and able to provide informed consent for the child's participation in the study

Healthy volunteers allowed
No

Age group

Child

Lower age limit
5 Years

Upper age limit
10 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Children identified through the Brief Eligibility and Safety Assessment as being at imminent risk of suicide, self-harm, or harm to others, requiring a level of care beyond that provided within the study
2. Children or caregivers with severe impairment related to mental, neurological, or substance use disorders (e.g. psychosis, severe intellectual disability, alcohol or drug dependence, or severe eating disorders) that would substantially limit their ability to participate in or benefit from the BLOOM intervention
3. Children identified as experiencing severe child protection concerns or violations that may compromise their immediate safety, including abuse, neglect, exploitation, violence, or other forms of harm, until appropriate safeguarding actions have been initiated and their safety has been assessed
4. Unaccompanied minors who do not have an authorised parent or legal guardian able to provide informed consent for participation in the research study

Date of first enrolment
16/11/2026

Date of final enrolment
15/01/2027

Locations

Countries of recruitment
Albania

Sponsor information

Organisation
Terre des Hommes

ROR
https://ror.org/05ay13t70

Funder(s)

Funder type

Funder Name
IF! Foundation

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available