

Assessing the impact of the I-Deal Life Skills Intervention on the psychosocial wellbeing of Syrian refugee children in Lebanon

Submission date 14/09/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/10/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/04/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Armed conflict poses multiple threats to children's mental health and psychosocial well-being (the way in which the environment affects mental wellbeing). In addition to exposing to children to experiences of violence and loss, organized violence often results in displacement (a type of defense mechanism), and disrupts all aspects of children's daily lives. Children must deal with parents who are highly stressed, with limited access to safe play and educational spaces, and with uncertainty regarding their future. They may also experience a loss of hope and control, as powerful events outside their control shape their lives in powerful and distressing ways. The I-Deal intervention is a themed life skills program aimed at strengthening children's resilience in the face of ongoing conflict, by enhancing life skills. The aim of this study is to assess the impact of the I-Deal intervention on children's psychosocial adaptation, compared with participation in structured recreational activity (SRA) groups that do not follow a theme.

Who can participate?

Syrian refugee children aged between 11-15 living in target communities. The study is also open to Lebanese children from neighboring communities, in keeping with War Child Holland's practice of making its programs available to refugee and host-country children and families.

What does the study involve?

320 Syrian refugee and Lebanese children living in nine communities in the Mhamara municipality of northern Lebanon are recruited into the study and randomly allocated to participate in either a 16-session life skills program called I-Deal or a 16 session active control condition using Structured Recreational Activities (SRA). I-Deal addresses key themes in the lives of war-affected and displaced children and adolescents: developing and managing social identity; relationships with peers and adults; dealing with emotions, including sadness and fear; and planning for the future. The SRA program does not explicitly foster life skills or address key themes, but instead is a set of fun, energizing activities meant to help children relax, play, and enjoy themselves in the supportive safety of trained adults. In both groups, sessions take place twice a week for eight weeks and are facilitated by adults recruited, trained, and supervised by War Child Holland-Lebanon staff. I-Deal sessions last 90 minutes, while SRA sessions last 30

minutes. At the start of the study, immediately after the program ends and then three months later, participants in both groups complete a number of questionnaires to measure their psychosocial wellbeing.

What are the possible benefits and risks of participating?

Participants in both groups are expected to benefit, although those who take part in I-Deal are likely to benefit more due to the structured nature of the program. In both groups, a reduction in stress and improvement in mood and peer relationships is expected. In the I-Deal group, moreover, increases in self-esteem, hopefulness and efficacy, in the capacity to develop and maintain social relationships are expected, as well as an increase in social behavior, and in the ability to cope effectively with difficult feelings, including anxiety, sadness, and fear. There is a small risk that some participants may feel uncomfortable answering the questions in the questionnaires with items that ask about stressful events and situations and about self-esteem and emotional wellbeing.

Where is the study run from?

The study is run from the Lebanon office of War Child Holland (Lebanon) and takes place in two settings: the Municipality building in Mhamara and a school located very close to the municipality building. Mhamara is located in northern Lebanon and is a major settlement area for Syrian refugees. Children in the study come from nine villages and refugee settlements in the area.

When is the study starting and how long is it expected to run for?

January 2016 to December 2017

Who is funding the study?

War Child Holland (Netherlands)

Who is the main contact?

Dr Kenneth E. Miller

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Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

WCH0001

Study information

Scientific Title

A pilot randomised controlled trial of the effectiveness of the I-Deal Life Skills Intervention for Syrian refugee children in Lebanon

Study objectives

A 16-session theme-based Life Skills intervention for war-affected children, the I-Deal program, will be superior to a 16 session structured recreational activity group in improving the psychosocial well-being of Syrian refugee children in Lebanon.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 01/03/2017, University of Balamand ethics committee.

Study design

Pilot randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Psychosocial wellbeing

Interventions

Current interventions as of 02/08/2017:

Participants are randomised to one of two groups using by a researcher/statistician outside of the study site using software for random allocation.

Group 1: Participants will receive the I-Deal Life Skills psychosocial support program, a 16 session universal (non-selective) group intervention for conflict affected children. Sessions are 90 minutes long, led by trained and supervised co-facilitators, and will meet twice per week for a total of eight weeks. Themes covered in the I-Deal intervention are Identity, Relationships with Peers and Adults, Dealing with Feelings (including grief, sadness, and fear), and The Future.

Group 2: Participants will receive a modified version of War Child Holland's Structured Recreational Activities intervention. The SRA is normally a drop-in group consisting of primarily non-thematic fun activities of different categories: warm-up/energizing; focused cooperative or individual creative activities; and relaxation/calming activities. For this study, only warm-up /energizing activities will be used, to ensure a clear and sufficient difference between the two interventions. Sessions of the SRA will be 30 minutes each, and will meet twice a week for a total of eight weeks.

Participants in both groups are followed up immediately post intervention (eight weeks) and three months later.

Previous interventions:

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Participants in both groups are followed up immediately post intervention (eight weeks) and three months later.

Intervention Type

Behavioural

Primary outcome measure

Psychosocial wellbeing is measured using the 14 item Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) at baseline, immediately post-intervention, and 3 months post-intervention.

Secondary outcome measures

Current secondary outcome measures as of 02/08/2017:

1. Psychological distress is measured using the 20 symptom items of the Strength and Difficulties Questionnaire (SDQ), completed by 11-17 year olds, at baseline, immediately post-

intervention, and 3 months post-intervention. The SDQ also includes a 5 item scale which we will use to assess Prosocial Behavior,

2. Psychological distress is also measured using the 25 item Strengths and Difficulties Questionnaire-Parent Version, completed by parents of 11-17 year olds, at baseline, immediately post-intervention, and 3 months post-intervention
3. Hopefulness and sense of agency are measured using the 6 item Children's Hope Scale at baseline, immediately post-intervention, and 3 months post-intervention
4. Self-esteem is measured using the 10 item Rosenberg Self-Esteem Scale at baseline, immediately post-intervention, and 3 months post-intervention
5. Social connectedness is measured using an 8 item sub-scale of the Social Connectedness scale at baseline, immediately post-intervention, and 3 months post-intervention

Previous secondary outcome measures:

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2. Psychological distress is also measured using the 25 item Strengths and Difficulties Questionnaire-Parent Version, completed by parents of 11-17 year olds, at baseline, immediately post-intervention, and 3 months post-intervention
3. Hopefulness and sense of agency are measured using the 6 item Children's Hope Scale at baseline, immediately post-intervention, and 3 months post-intervention
4. Self-esteem is measured using the 10 item Rosenberg Self-Esteem Scale at baseline, immediately post-intervention, and 3 months post-intervention
5. Moderation of outcomes by level of stress exposure is measured using a stress exposure scale developed for this study will be administered at baseline

Overall study start date

01/02/2016

Completion date

31/08/2017

Eligibility

Key inclusion criteria

1. Syrian refugee children; added 02/08/2017: and Lebanese children
2. Between ages 11-15
3. Living in target communities

Participant type(s)

Other

Age group

Child

Lower age limit

11 Years

Upper age limit

15 Years

Sex

Both

Target number of participants

Total sample is 320 (160 per arm)

Total final enrolment

325

Key exclusion criteria

1. Psychosis
2. High level of aggressive behavior that disrupt intervention

Date of first enrolment

01/01/2017

Date of final enrolment

31/01/2017

Locations

Countries of recruitment

Lebanon

Study participating centre**War Child Holland**

3rd Floor, Mother and Child Welfare Center
Hussein Ouweiny Street
Beirut
Lebanon

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Sponsor information

Organisation

War Child Holland

Sponsor details

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Sponsor type

Charity

Website

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ROR

<https://ror.org/01tq9ra93>

Funder(s)

Funder type

Charity

Funder Name

War Child Holland

Results and Publications

Publication and dissemination plan

Planned publication of findings in a high-impact peer reviewed journal.

Intention to publish date

31/10/2019

Individual participant data (IPD) sharing plan

The study team are currently working on identifying the repository where the data will be stored. Once an appropriate repository have been identified, they will be happy to provide the name, persistent weblink and other information. The types of data that will be stored include quantitative (questionnaire-based) and qualitative (focus group) data.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/11/2020	25/04/2022	Yes	No