“Effectiveness of a climbing (bouldering) intervention on psychological wellbeing for adolescents in the Bekaa Valley, Lebanon".

Version 1 from 24.01.2022

Table of contents

List of Figures

1. Summary of the project/ brief description acc. to the requirements of the Ethics committee of the Antonine University, Beirut

Title	**Effectiveness of a climbing (bouldering) intervention on psychological well-being for adolescents in the Bekaa Valley**
Research subjects	Adolescents (12-19) living in the Bekaa Valley • Prisoners : no prisoners involved • Pregnant women: pregnancy is an exclusion criterion • Victims of crime: not targeted specifically, but no exclusion criterion • People with illness (physically or mentally): not targeted specifically, but no exclusion criterion The project will lead to results that will improve our understanding of the state of the minor participants. The research will lead to generalizable results.
Place	Arcenciel Centre, Damascus-Road, Taanayel, Central Bekaa, Lebanon
Researchers and their qualification	• KL: Researcher, Psychologist, Psychotherapist, Lecturer in Medical Psychology • CN: Clinical associate professor, Antonine University, Lebanon. • SR: BSc, PhD. Associate Professor, School of Psychiatry, UNSW Sydney, Australia • BB: ClimbAID, BA in Social Science, Switzerland / Lebanon
Exclusion/Inclusion criteria:	(1) age between 12 and 19 (2) residing in Central Bekaa, Lebanon (locals and refugees) (3) informed consent of adolescent and his/her legal guardian (4) absence of absolute contraindications to participation in bouldering (for example pregnancy)
Procedures and measures that will be adopted to ensure the protection of vulnerable participants	During intervention Adverse Events (AEs) including suicidal behavior and accidents with resulting injuries are documented by the facilitators in the IG and by the study headquarter for the CG. Regular interim evaluations are made (at least once per month). In case of an unnatural accumulation of AEs in the IG, the intervention will be stopped. In case of an accident during the intervention, the participant will be taken to an appropriate medical care provider. Fees are paid for by the NGO ClimbAID and the insurance of its Lebanese partner Arcenciel (owner of the land and facility).
Collection of Data Survey / Questionnaire	• Questionnaires: X Personally X Online X Email □ Post X Phone The preferred collection strategy is face to face. If this is not possible, data collection via other ways will be used in order to minimize the amount of missing data (for example if participants move to another camp) Other ways: • Interview: X Face to face □Focus group □Oral history □Other: • Observation: none • Archived data: none • Tasting: none • Examination specimen of human tissue: none • Recordings: X Audio □ Video □ Photo • Purpose of recording: 4 - Other: qualitative data analysis; content will not be shared anywhere outside the research team
Recruitment	Need to recruit participants? X Yes □No Recruitment methods: X Personally X Media X Post X Social media □Phone □Email □Other: Participants approach method: Adolescents will be recruited through several outreach channels (schools, other non-profits, social networks of current participants, outreach campaigns in informal tented settlements, etc.). Criteria for the selection of participants: see inclusion and exclusion criteria
Authorizations	Every adolescent and his or her legal guardian (parent or relative in charge in case there is no parent available) gives the written informed consent to participate in the study.
Risks	Possible risks: Physical risks in supervised climbing are very small. In the last 4 years with approx. 2500 participant hours of climbing only very few injuries (twisted ankles) occurred. Methods to minimize risks:

	All climbing advisors have completed training with “Coaches across Continents” and are trained in child protection and mental health first aid. Supervision is granted by a climbing supervisor of the Swiss Alpine Club who also trains every trainer in safety rules. Climbing gear is checked regularly and replaced according to the guidelines of the Swiss Alpine Club. No risk for third parties. □ Can this project lead to the discovery of a new medical or psychological condition within the participants? Yes. Through psychological questionnaires indications of mental illness emerge. If so, we would approach the participant and his/her legal guardian and inform about local support services. No valid medical diagnoses are made during the project.
Benefits	a. To individuals: As pilot data show, participants can benefit from the climbing intervention in terms of quality of life and overall wellbeing. The minimum benefit would be 16 hours of physical activity shared with others. b. To society: A new and relatively economical method may be derived from this research and may be used to support highly vulnerable groups and help improve their quality of life.
Data Protection	1- How will you protect the identity of the participants? Names and contact details of the study participants are recorded electronically and stored password-protected on a separate device without internet access. Every participant is assigned to a randomly generated code after inclusion in the study. All further data gathered through questionnaires are pseudonymized using accredited data systems such as Upshot. Access to the patient data as well as the coding table is restricted to the scientists involved in the conduct of the study. Paper data sheets are stored in a locker. The data will only be passed on to third parties in the context of publications in verified data repositories. Here, complete anonymization will be ensured. If a participant revokes his or her consent, his or her complete data record may be deleted upon request. 2- How will you protect the Data? Electronically stored data (which is pseudonymized) will be protected by the use of accredited data handling systems such as RedCap or Upshot. 3- Where do you plan to save the Data? See above 4- How long the data will be kept? According to Lebanese law, all personal data will be stored for 5 years 5- Who will have access to this data? CN, SR, KL, BB will have access to the personal data as well as the study coordinators during data collection. Researchers and their team have access to pseudonymized data during the analysis. 6- In case of tissue specimens have been collected, where will these specimens be kept? for how long? Who will have access to these specimens? Not applicable
Results and publication	1- Publication: Will the results of this research be published? How do you intend to disseminate these results? Yes. We aim to publish all results in international peer-reviewed journals. The study will also be registered at ISRCTN. 2- Financial gains: Will the participants in this project or the researchers reap the financial benefit of this project? No Is there a risk of conflict of interest? No

2. Abstract

Background:
There are currently 1,5 million refugees living in Lebanon, many of them minors. These refugees often live under severe conditions and there is a call for action as their adverse life events can cause physical and psychological issues. Research indicates that physical activity has a major positive impact on physical and mental stress. Climbing has been shown to be an effective mode of physical activity that can improve various physiological and psychological parameters. The aim of the study is to test the effect of a manualized climbing group intervention on the wellbeing, distress, self-efficacy, and social stability of adolescent refugees in Lebanon. In addition, the mechanisms behind psychological changes will be investigated.
Methods:
Approximately 160 participants, aged 12 to 19 years, will be included in the study. Half of these start immediately with the intervention (IG), while the other half needs to wait for 8 weeks (i.e. the waitlist control group CG) and then gets the possibility to participate in the same intervention as the IG. Participants will be recruited from various settlements and towns in Central Bekaa. The primary outcome measure is the difference between the IG and the CG in overall mental well-being (WEMWBS)

at the end of the 8-week intervention. Here, a superiority of the intervention is expected (effect size of Cohen's d ≥ 0.6). Secondary outcome measures comprise distress symptoms (K-6 Distress Scale), self-efficacy (General Self-Efficacy Scale (GSE)) and social stability outcomes (2 items from the ARK – Regular Perceptions Survey). In addition, sociodemographic data such as gender, age, height, weight (BMI), grade level, nationality, refugee vs. host community status as well as information about medication, climbing experience will be collected. Furthermore, potential mechanisms of change, and implementation factors as barriers and facilitators will be investigated in qualitative interviews with 40 participants (20 after 4 weeks of climbing and another 20 after the full circle of 8 lessons). Participants in the control group will not receive any additional intervention services during their waiting time, but will have the option of receiving usual care. In terms of statistical analyses, univariate (T-tests or corresponding non-parametric procedures), as well as multivariate tests (regression analysis; analysis of variance), will be employed. If significant differences between the groups emerge at baseline, propensity score matching will be used to account for non-randomization. The probability of error is set at p = .05. The partially standardized interviews will be analyzed through a Qualitative Content Analysis according to Mayring.
Intervention:
The climbing intervention will be conducted in weekly 2-hour sessions over an 8-week period. During these sessions, participants learn various climbing techniques, as well as educational content intended to strengthen the participants' self-worth, give them a sense of belonging and promote their "life skills." Sessions will be structured by a detailed manual and led by specially trained ClimbAID staff supported by volunteers.
Hypotheses:
It is hypothesized that the climbing intervention will have a beneficial effect on participants' wellbeing assessed with the WEMWBS (Cohen’s d > 0,6).
Registration: the study will be registered at the ISRCTN platform (current-controlled trials).

3. Scientific background

3.1 State of the research

Lebanon is the country that has taken in the most refugees worldwide in relation to its population. Among them are an estimated 1.5 million Syrian refugees forced to leave their homes due to the war. In addition, there are about 18,500 refugees from Ethiopia, Iraq, Sudan, and other countries, and about 200,000 Palestinian refugees under the mandate of UNRWA (UN Refugee Agency, 2020). Lebanon is already severely burdened by an economic crisis, inflation, unemployment and outdated infrastructure. As a result of the large number of refugees of various origins, tensions may also arise that threaten the country's social stability. Since there are no formal refugee camps in Lebanon, those seeking protection live in many small, simple and sometimes overcrowded temporary shelters scattered throughout the country. The winters, which are usually very wet and cold, can flood the dwellings in particular, making living conditions at this time of year extremely difficult. Many refugees also have little or no financial resources. About half live below the poverty line or survive on jobs in the informal sector. Nearly 30 percent of the total registered refugee population in Lebanon are children (UN Refugee Agency, 2020).
Adverse living conditions, human rights violations, and ongoing stressors have a detrimental effect on the mental health of refugees. Common support systems often break down, are overburdened or limited during humanitarian crises. Thus, it is necessary to protect and promote the mental health of young refugees, especially in resource-poor settings, also considering that mental and physical symptoms are closely coupled. People affected by mental health conditions are twice as likely to suffer cardiovascular, infectious, respiratory, or metabolic diseases compared to the general population (Firth et al., 2019) and have a lower life expectancy (Thornicroft, 2011). Thus, appropriate interventions need to be applied early to be able to prevent physical comorbidities in mentally distressed individuals. Services offered by nonprofit organizations typically have limited reach, leaving many young refugees without access to support programs (Wells, Némorin, Steel, Guhathakurta, & Rosenbaum, 2019). There is a need for scalable, low-threshold, evidence-based psychosocial interventions that simultaneously strengthen mental health in addition to physical health. In this regard, group interventions represent cost-effective services that could serve large numbers of people.

Sports and physical activity programs represent a potential group intervention to improve the physical and mental health of young refugees. Physical activity is described by WHO (2009, as cited in Ahmed, Mahmuda, & Alam, 2019, p. 285) as "any bodily movement produced by skeletal muscles that results in energy expenditure." Sport represents a subset of physical activity and describes any type of exercise that helps to stay physically fit and improves psychosocial well-being and social interaction (Ahmed, Mahmuda, & Alam, 2019). In non-humanitarian settings, the positive effects of sport and physical activity have been widely researched. Regular participation in sport is associated with improvements in symptoms of depression (Cooney et al., 2013), post-traumatic stress symptoms (Rosenbaum, Vancampfort, et al., 2015), eating disorders (Blanchet et al., 2018; Moola, Gairdner, & Amara, 2013), or substance dependence (Wang, Wang, Wang, Li, & Zhou, 2014). In addition, exercise is thought to have a preventive protective effect with respect to the onset of mental illness (e.g. Harvey et al., 2018). Physical activity is further capable of increasing self-esteem and energy levels, as well as improving well-being and overall quality of life (Biddle & Asare, 2011; Janssen, 2007, as cited in Ahmed et al., 2019). As a psychosocial intervention, sports programs create a healthy environment where participants can manage their stress in a positive way, form team friendships, and experience a sense of belonging. To date, little research exists that has focused on the effects of psychosocial sport interventions on the mental health status among people affected by adverse living conditions and flight. However, existing literature illustrates that sport and physical activity in the context of humanitarian assistance are capable of improving the psychosocial well-being of young refugees (Rosenbaum et al., 2021): for example, a martial arts program for young refugees in Australia had positive effects on interpersonal skills, sense of responsibility, and discipline (Momartin, Coello, Pittaway, Downham, & Aroche, 2019). In Bosnia and Herzegovina, social connectedness was restored among diverse communities in conflict and skills such as teamwork or self-confidence were strengthened (Kvalsund, Nyheim, & Telford, 2004, as cited in Ahmed et al., 2019). For survivors of torture, trauma-sensitive soccer proved to be a critical factor in regaining access to one's body, building social relationships, and learning to cope with stressful events (Horn et al., 2019). A study of children and adolescents holds that after disasters, sports and exercise are able to promote emotional and social stabilization and improve resilience (Ley, Rato Barrio, & Koch, 2018). Sport is also a highly accepted and culturally well-integrated way to reduce stress but access to sport is often severely limited, particularly in refugee camps (Ahmed et al., 2019; Wells et al., 2019).

3.2 Own preliminary work

In order to prove the effectiveness of a boulder psychotherapy during depression, one member of the research group (KL) already conducted two controlled randomized studies: In the pilot study from spring 2013 to spring 2015, conducted at the University Hospital Erlangen, the effectiveness of a boulder psychotherapy compared to a waiting control group was shown (Luttenberger et al., 2015). The effects appeared stable over the entire follow-up period of a total of 10 months after the end of therapy (Schwarz et al., 2019). Even when controlling for general physical activity in the second part of the study, it was found that the effects of boulder psychotherapy were still significant and exceeded the effects of non-specific activation (Stelzer et al., 2018).
A randomized controlled 3-arm multicenter study (Dorscht et al., 2019) showed the superiority of boulder psychotherapy (BPT) over an active control group (digitally supported sports program) (Karg, Dorscht, Kornhuber, & Luttenberger, 2020), as well as the non-inferiority of BPT compared to cognitive behavioral therapy in the group (Luttenberger et al., 2021). Another member of the research group (SR) has ample experience in the conduct of research regarding physical activity interventions for trauma exposed populations (Rosenbaum, Sherrington, & Tiedemann, 2015; Rosenbaum, Vancampfort, et al., 2015) and also in conducting studies in humanitarian settings (Fischer, Zarate, Mozumder, Elshazly, & Rosenbaum, 2021; Rosenbaum et al., 2021; Wells et al., 2019).

3.3 Question

Building on the data of the pilot study, the study applied for here, will investigate the effectiveness of an 8-week climbing intervention on psychological well-being. Furthermore, attention will be paid to effects of the climbing intervention on symptoms of depression and self-efficacy as well as social stability. Finally, possible mode of action factors of the climbing intervention will be recorded.

Climbing interventions are hypothesized to be effective because of several factors:

- Specific climbing-associated factors such as mindfulness level, body experience, emotion exposure while climbing, emotion management, etc.
- Specific factor-supportive content
- Unspecific factors such as social interaction and group experience
- The non-specific factor sports activation in general

4. Study objectives

4.1 Objective

The aim of the study is to test the effectiveness of a climbing intervention among adolescent refugees in Lebanon, Bekaa region. It is suspected that the climbing intervention has a beneficial effect on the psychological well-being of the participants.

The intervention is implemented by ClimbAID, a non-profit organization that uses climbing as an intervention tool to build inclusive communities, improve mental wellbeing and address social issues through projects in Switzerland, Lebanon and Greece.

4.2 Expected results/hypotheses

The primary outcome is psychological well-being. The intervention group (IG) is expected to be superior to the waitlist control group (CG) (effect size of Cohen's d ≥ 0.6).

The associated hypothesis is as follows:

H1. Adolescents participating in the climbing intervention (IG) improve significantly more in terms of their psychological well-being (as measured by the score of the WEMWBS) than adolescents assigned to the control group (CG).

Secondary outcomes will be symptom severity of distress, self-efficacy, and social stability outcomes. Improvement is expected in the intervention group (IG) compared to the CG without climbing program.

The associated hypotheses are as follows:

H2. Adolescents participating in climbing intervention (IG) improve significantly more in terms of distress severity (as measured by the score of the K-6 Distress Scale) than adolescents assigned to the control group (CG).

H3. Adolescents participating in climbing intervention (IG-CG) improve significantly more in terms of general self-efficacy (as measured by the score on the GSE scale) than adolescents assigned to the control group (CG)

H4. Adolescents participating in climbing intervention (IG) improve significantly more in terms of social stability attitudes (as measured by 2 items from the ARK Regular Perception Survey) than adolescents assigned to the control group (CG).

Additionally, qualitative interviews will be held with at least 40 members of the IG to extract possible factors of effect of climbing intervention as well as intervention barriers and facilitators.

5. Target figures

5.1 Primary target variables

The primary outcome measure will be the adolescents' overall mental well-being as measured by the WEMWBS (Warwick-Edinburgh Mental Well-Being Scale) at all 3 measurement time points (before start of therapy for the IG, after the IG-therapy phase and after the CG intervention phase).

5.2 Secondary target variables

As secondary outcome measures, the variables distress severity (as measured through the K-6 Distress Scale(Prochaska, Sung, Max, Shi, & Ong, 2012)), self-efficacy (as measured through the GSE Scale (Crandall, Rahim, & Yount, 2015)) and social stability attitudes (as measured through two items from the ARK Regular Perception Survey (Regular Perception Surveys on Social Tensions throughout Lebanon, Wave X — ARK) will also be collected at all measurement time points. Possible effect factors will be collected in the intervention groups using qualitative data from half-standardized interviews. Half of these interviews will be conducted during the climbing program, whereas the other half will be conducted after completion of the climbing program.

5.3 Influencing variables/ disturbance variables

The following variables are recorded as possible influencing variables or confounding variables in the questionnaire format:

- Sociodemographic data: Gender, age, height, weight (BMI), grade level, nationality, household income, living conditions.
- Use of medication
- Climbing experience

6. Study design

6.1 Design

The research is designed as a 2-arm study, with implementation of a climbing intervention program for Lebanese and foreign adolescents including refugees living in the Bekaa region, Lebanon, and data analysis in Erlangen, Germany.

6.2 Study arms

Climbing intervention (Arm 1; IG climbing groups) will be chosen as intervention and compared against a control group (Arm 2; CG).

The CG does not receive any study specific offer during the IG-intervention but is invited to participate in the upcoming circle of the climbing program. Members of the CG are therefore offered the same intervention as the IG after their waiting period.

6.3 Distribution to IG and CG

To increase adherence to the study requirements, allocation to the intervention or waitlist control group may be self-selected by participants as long as participants participate at all data collection time points. Groups should be balanced in terms of gender and age.

7. Study population

7.1 Inclusion and exclusion criteria

The target population of the study includes adolescents (locals and refugees) aged 12-19 living in the Bekaa valley in Lebanon.

Inclusion criteria:
- Age between 12 and 19
- Informed consent for participation in the study from adolescents as well as legal guardians (adult relatives), in particular for data collection, anonymized data storage,
- Availability and possibility to come to the climbing intervention and to participate in the data collection

Exclusion Criteria:
- Self-harming behavior within the last month/ No collusion ability with regard to suicidality
- Presence of current serious mental illness (e.g., psychosis, mania)
- Aggressive behavior against trainers or other participants
- Physical contraindications (physical ailments or pregnancy).
- BMI < 18.5 or > 35
- Participate(d) already in a program of ClimbAID

7.2 Intended sample size

Power analysis indicates that the IG and CG each need to comprise 52 study participants at the T2 posttest data collection point. Assuming a drop-out rate of 20% per intervention half, 80 participants thus need to be enrolled in the IG and the CG, respectively. Hence, at least 160 adolescents need to be included in the study, distributed among the six climbing groups (each consisting of 12-14 participants) and the control group. Including the waitlist control group (receiving treatment after the study period) up to a total of 160 adolescents will thus be provided with a climbing program.

7.3 Recruitment channels and measures

Adolescents from the refugee and host communities in Lebanon will be included in the study. In order to provide access to the climbing program to as many adolescents as possible and to ensure high representativeness of the sample, the adolescents will be recruited through several outreach channels (schools, other non-profits, social networks of current participants, outreach campaigns in informal tented settlements, etc.). Parents or (legal) guardians can apply through an online form for participation in the program and thereby accept the inclusion of their children/adolescents in the study. The adolescents are then invited for a first trying session to check whether they want to participate. If they like the activity, the adolescents are asked to fill in the screening and the informed consent and then the pre-test questionnaire. For this purpose, information materials, including posters, flyers, and letter texts, are to be prepared and distributed through diverse channels. Informational events get planned to inform about the climbing program.

ClimbAID, as the responsible NGO, has already conducted a study in Lebanon using these recruitment routes.

8. Course of studies

8.1 Procedure for informing and obtaining consent

Participating adolescents will be provided with educational and informed consent forms prior to the start of the study (see Appendix).

8.2 Intervention

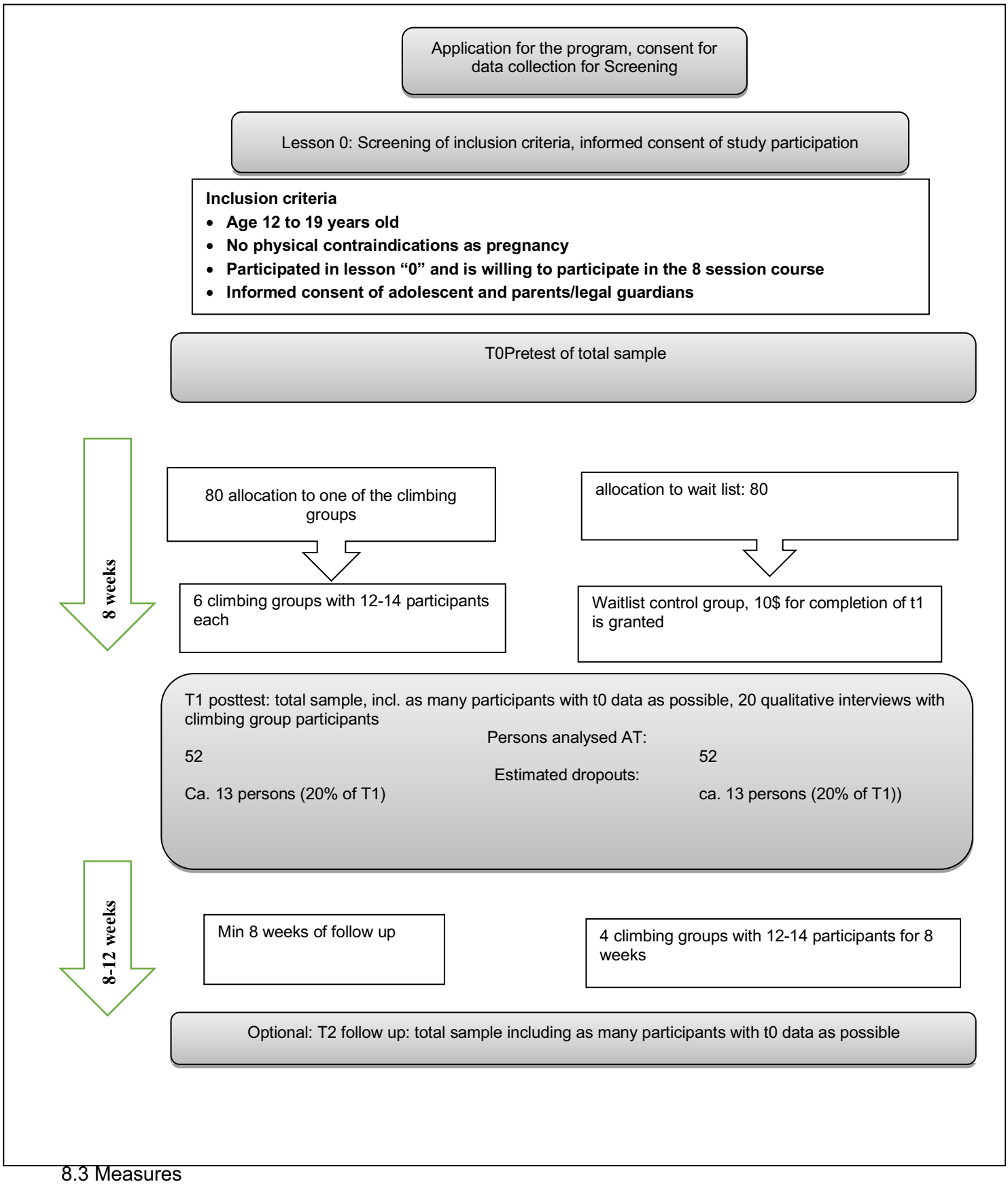
Interventions take place once a week for a period of 120 minutes over a 8-week period.

The intervention group receives a climbing intervention which combines movement elements with educational content. The associated manual is carried out by two instructors, who are specially trained in safety rules by a climbing instructor of the Swiss Alpine Club. The instructors are also trained in child protection, mental health first aid and coaching by several NGOs including “Coaches across Continents” and “Warchild”. The sessions are designed to strengthen the participants' self-worth, give them a sense of belonging, and promote their "life skills." The associated session-specific topics can be found in Table 1.

Hour and theme
1 + 2 trust
3 + 4 teamwork and cooperation
5 + 6 communication and conflict resolution
7 + 8 problem solving and decision making

Table 1: Meeting topics of the IG

The control group initially does not receive a climbing offer; all participants are rewarded with 10 $ after participating in t1. After completion of the IG-CG climbing cycle (8 weeks), the control group is also allowed to participate in the climbing program.



8.3 Measures

Standardized questionnaires are used to record the target variables. Data collection will be in self-report format.

The following instruments are planned (please note that only two items from the ARK Regular Perception Survey will be used):

Priority	Full Measure Title	Abbreviation	Construct
Primary Outcome Measure	Warwick-Edinburgh Mental Well-being Scale	WEMWBS	Overall mental wellbeing
Secondary Outcome Measure	Kessler Psychological Distress Scale	K6	Distress Severity
Secondary Outcome Measure	General Self-Efficacy Scale	GSE	Self-efficacy
Secondary Outcome Measure	ARK Regular Perception Survey	ARK	Social Stability Outcomes

In addition, qualitative data will be gathered from a number of participants in the intervention groups. These data will be collected through qualitative interviews by trained personnel in a single blinded fashion in order to investigate the acceptance and effect factors of the climbing program.

8.4 Measurement points

Surveys will take place for all groups (IG and CG) before the start of the intervention (t0, pretest), 4 weeks after the start of the intervention (t1), immediately after the end of the intervention (t2, post-test), and 8 weeks after the end of the intervention (t3, follow-up). For the individual participant, the study duration is approximately 16 weeks with 8 weeks of intervention in each case (see Fig 1).

8.5 Total duration of the study

The total duration of the study is 12 months.

9. Risk-benefit analysis

9.1 Risks

The greatest risk of a climbing (exactly bouldering) intervention is sports injuries. Bouldering takes place without a rope on walls no more than 4 m high, so the jump height is no more than 2.5m. The climbing routes are predefined, with the coloring of the holds and footholds providing information about the difficulty of the route. The easiest routes are easily manageable even for inexperienced participants. The climbing wall is covered with thick foam mats (mat thickness approx. 20 cm), which cushion jumps or possible falls. Additionally, moveable crashpads are used. A fall can also be avoided by using non-route (different color) holds or footholds. As part of the climbing program, participants are instructed to completely avoid jumping off.
All IG-CG youth receive an introduction to safety rules and jump training. If participants and/or climbing instructors do not trust themselves/the young person to jump off safely, climbing will only take place at a jump height of approx. 50 cm across the wall. Nevertheless, injuries due to falls etc. cannot be completely ruled out, as with any sporting activity.
A recent study (Neuhof, Hennig, Schoffl, & Schoffl, 2011) on the frequency of injuries in sport climbing on almost 2000 climbers showed an average of 0.2 injuries per 1000 h climbing. In the last 4 years of ClimbAID's engagement in the Lebanon only one injury (twisted ankle) in at least 2000 participant climbing hours was caused by the climbing program.
The likelihood of falls resulting in significant injury is generally considered to be rather low in bouldering and is probably even lower with the guidance of a climbing instructor. Minor injuries, such as abrasions or strains/stretching of tendons and ligaments, are most likely to occur. Overall, the risk does not exceed that of other sports activities. The expected positive effects on the psychological well-being of adolescent refugees far exceed the possible risks of injury.

As with any activity involving transport in a motor vehicle, there is always a risk of injury, permanent damage or death from accidents. ClimbAID makes every effort to keep the risk of accidents as low as possible and therefore only works with reliable and trustworthy transport service providers who comply with the relevant legal provisions and safety regulations.

9.2 Benefit

In any case, all trial participants will receive a free 8-week climbing intervention, which is expected to have a positive impact on physical and mental health based on preliminary findings.
In the long term, there is an opportunity to develop a mental health support program that specifically addresses the needs of young Arab refugees and marginalized adolescents in the Lebanon. Findings on the effectiveness of such a climbing intervention would expand the range of current support programs. Group implementation is also particularly advantageous, as it is more cost-effective than individual grants.
From a scientific perspective, the controlled intervention study will provide evidence-based knowledge on possible interventions and effect factors in humanitarian assistance to refugees, so there is a clear contribution to knowledge gain.

9.3 Termination criteria

Termination of the program on the part of the climbing leader is possible due to the following factors:

- Withdrawal of consent
- Subsequent determination of the existence of exclusion criteria (see above).

Cancellation of the climbing program on the part of the participants is possible at any time, even without giving reasons.

8.4. During intervention Adverse Events (AEs) including suicidal behaviour and accidents with resulting injuries are documented by the trainers/facilitators in the IG and by the study headquarter for the CG. Regular interim evaluations are made (at least once a month) and, in case of an unnatural accumulation of SAEs in the IG, the intervention will be stopped. In case of an accident during the intervention, the participant is taken to an appropriate medical care provider. Fees are paid for by the NGO ClimbAID and the insurance of its Lebanese partner Arcenciel (owner of the land and facility).
Definition of AEs:

- Mild AEs in the intervention group: all sort of bruises or scratches or other minor superficial injuries that are transient and do not require treatment
- Moderate: injuries like ligament ruptures or sprains, broken bones in legs or arms, that are transient but require medical treatment
- Severe AEs: severe head injuries, injuries of spinal cord, death, suicidal attempts

Termination rules: in case of one SAE in the intervention group during intervention, the programme is stopped until further clarification of the causal relation with the intervention is reached.
In case of moderate AEs, treatment is stopped, if there are three more AEs in the intervention than in the waitlist group that are in direct causal relation to the intervention. Mild AEs are recorded but do not result in a termination of the programm.

9.4 Statement on medical justifiability

Information on physical illnesses is requested at the beginning of the study. In case of physical contraindications (e.g., knee diseases, pregnancy), exclusion from the study will take place. In case of doubt, medical advice will be sought.

10. Biometrics

10.1 Case number estimation

Biometric design was performed using G*Power software with a two-tailed alpha of .05 and beta of 90% and an estimated effect size of cohen's d = .55. This resulted in a necessary sample (as treated AT) of at least 52 members per group at T2. As the dropout rate in this difficult context is hard to estimate we include at least 160 persons at T0.

10.2 Planned statistical methods

Univariate (T-tests or corresponding non-parametric procedures), as well as multivariate (regression analyses, variance analyses as mixed ANOVA) statistical procedures are used to test the questions. The probability of error is set at p = .05. Due to the use of structured interviews, a high completeness of the data can be assumed. In case of missing data, imputation procedures (e.g. EM imputation) are performed. Because of non-randomisation, analysis via propensity score matching is planned if groups show significant differences in important sociodemographic variables.

11. Data management and data protection

11.1 Data acquisition and storage

Data collection will be based on questionnaires at the four measurement time points (t0, t1, t2, t3) via data management tools such as RedCap or Upshot. After each survey wave, the data will be transferred into an analyzable, electronic format (IBM SPSS Statistics) by trained personnel at the study center.

11.2 Anonymization

Names and contact details of the study participants are recorded on the screening sheet and assigned to a randomly generated code after the inclusion of the participants in the study. All electronic data are stored pseudonymously using the code, and personal data are stored in paper form in a locked cabinet. Access to the patient data as well as the coding table is restricted to the scientists involved in the conduct of the study.

11.3 Data transfer

The data could only be passed on to third parties in the context of publications in verified data repositories and would only be anonymized.

11.4 Revocation/ Data deletion

If a participant revokes his or her consent, his or her complete data record may also be deleted upon express request.

12. Project Management

Research Team:
Charbel Najeem Clinical Assistant Professor, Antonine University, Lebanon. Ph.D. researcher, Gent University, Belgium.

PD Dr. Katharina Luttenberger (Department of Medical Psychology and Medical Sociology of the Psychiatric and Psychotherapeutic Clinic, Friedrich Alexander University Erlangen-Nuremberg)

Simon Rosenbaum
BSc Phd, Associate Professor, School of Psychiatry, UNSW Sydney, Australia

Beat Baggenstos
BA in Social Science, Managing Director at ClimbAID, Switzerland / Lebanon.

The study managers, as the overall responsible parties, monitor the progress of the project, the fulfillment of milestones, and compliance with relevant regulations.

PD Dr. Katharina Luttenberger

Charbel Najem

Simon Rosenbaum

Beat Baggenstos

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