Translations and adaption of outcome, health economic, and implementation measures in FLOURISH (Phase 1)

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Statement of Originality

This report contains original unpublished work except where clearly indicated otherwise. Acknowledgements of previously published material and of the work of others has been made through appropriate citation, quotation or both. This report summarizes the work on translation and measures of the FLOURISH Consortium.

The sole responsibility for the content of this paper lies with the authors and do not necessarily reflect those of the European Union or UK Research and Innovation (UKRI). Neither the European Union nor the granting authorities can be held responsible for them.

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List of Abbreviations

Abbreviation	Expansion
ALTERNATIVA	Institute for Marriage, Family and Systemic Practice
FLOURISH	Family – Focused Adolescent & Lifelong Health Promotion
PLH	Parenting for Lifelong Health for Parents and Teens
PLH-FAT-T	Parenting for Lifelong Health Facilitator Assessment Tool for the Parents and Teens intervention
ODK	Open Data Kit
HAT	Helping Adolescents Thrive toolkit
RCADS	Revised Child Anxiety and Depression Scales
WHO	World Health Organization
WHO-5	World Health Organization – Five Well-Being Index
PECUNIA RUM	PECUNIA Resource Use Measurement instrument
OxCAP-MH	Oxford Capability Questionnaire – Mental Health
UNICEF	United Nations Children's Fund
EQ-5D-5L	5-level EQ-5D version
EQ-5D-Y	Youth EQ-5D version

1 Introduction

1.1 FLOURISH study

Family-Focused Adolescent & Lifelong Health Promotion (FLOURISH) study is focusing on adapting, optimizing, and evaluating the implementation, effectiveness, and cost-effectiveness of a program package for adolescents and their caregivers in the Republic of Moldova and North Macedonia. The study is conducted in two health networks, Institute for Marriage, Family and Systemic Practice (ALTERNATIVA) and Health for Youth Association. ALTERNATIVA in North Macedonia is a network that includes psychologists, social workers, and family therapists. Health for Youth Association in the Republic of Moldova represents youth-friendly clinics that offer prevention and treatment in sexual and reproductive health, mental health, substance use and violence prevention.

The intervention package is based on the Parenting for Lifelong Health (PLH) for Parents and Teens, and additional intervention components, including the Helping Adolescents Thrive (HAT) comics and toolkit. More details about the project can be found on the project webpage: https://www.flourish-study.org/about.html.
The project is organized in three main phases. Phase 1 (program adaptation and piloting, 2023-2024) is a small-scale feasibility pre-post trial with 60 primary caregivers and their 10-14-year-old children. Phase 1 examines the feasibility of the intervention, its implementation, evaluation procedures and methods, as well as preliminary program effects. More details about the Phase 1 study design can be found on the clinical trials registry (clinicaltrials.gov NCT05930535) and in the published protocol (Shenderovich et al., 2023). The full version is found in the FLOURISH study protocol deliverable (contact Coordinator, heather.foran@aau.at for more information).

Phase 2 (factorial trial and process evaluation, 2024-2025) is a randomized full factorial study (2x2x2) that examines three intervention components (on versus off), and their effects, interactions, consequences, and costs: HAT comics, adolescent peer support, and attendance incentives. Finally, Phase 3 (hybrid implementation-effectiveness randomized trial and process evaluation) will test the effectiveness and cost-effectiveness of the adapted program from Phase 2.

The purpose of this report is to provide an overview of the processes undertaken by the FLOURISH consortium in Phase 1 of the FLOURISH study for translating and adapting the measures used to assess intervention outcomes, implementation and health economic aspects.

1.2 Overview of the measures translated and adapted for the FLOURISH project

This section provides an overview of the measures translated and adapted in FLOURISH in Phase 1, and the following sections discuss the methods used in more detail.

Intervention outcome measures

All adolescent and caregiver questionnaire measures were translated and/or adapted for the FLOURISH project. The measures are described in more detail in the trial registration (https://clinicaltrials.gov/study/NCT05930535?term=flourish&rank=9) and briefly in the pilot study protocol (Shenderovich et al., 2023).The following Tables 1 and 2 provide an overview of the primary and secondary outcome measures.

Table 1.

Primary Outcomes

Construct	Respondent	Measure
Adolescent emotional problems	Adolescents	- The Revised Child Anxiety and Depression Scales (RCADS), anxiety and depression subscales (Krause et al., 2021) - Child Behaviour Checklist 6-18, internalising subscale (Achenbach & Rescorla, 2001) - Youth Self-Report 11-18, internalising subscale (Achenbach & Rescorla, 2001; Ivanova et al., 2007)
Adolescent behaviour problems	Adolescents	Youth Self-Report, rule-breaking and aggressive behaviour
	Caregivers	Child Behaviour Checklist, rule-breaking and aggressive behaviour
Adolescent well-being	Adolescents	World Health Organization-Five Well-Being Index (WHO-5) (Topp et al., 2015; WHO, 1998)

Table 2.

Secondary Outcomes

Construct	Respondent	Measure
Communication	Adolescents & Caregivers	Child-Parent Communication Apprehension scale, total score (Lucchetti et al., 2002)
		Family Assessment Device-FAD, general functioning subscale (Epstein et al., 1983)
Involved parenting	Adolescents & Caregivers	Alabama Parenting Questionnaire (Frick, 1991), involved parenting and parental supervision/monitoring subscales.
Harsh parenting	Caregivers	Alabama Parenting Questionnaire (Frick, 1991), corporal punishment subscale.
Adolescent emotional problems	Adolescents	The Revised Child Anxiety and Depression Scales (RCADS), total score (Chorpita et al., 2005; Krause et al., 2021)
Adolescent behavior problems	Caregivers	Child Behavior Checklist 6-18, externalizing behavior (Achenbach & Rescorla, 2001)
Loneliness	Adolescents	UCLA-8 Loneliness scale, total score (Roberts et al., 1993)
	Caregivers	Revised UCLA-6 Loneliness scale, total score (Wongpakaran et al., 2020)
Social support	Adolescents & parents	Medical Outcome Study Social Support Survey, emotional and affectionate sub-scales (Sherbourne & Stewart, 1991)
Parents wellbeing	Caregivers	WHO-5 Well-Being Index, total score (WHO-5; Topp et al., 2015; WHO, 1998).
Parents psychological distress	Caregivers	The Patient Health Questionnaire – 9 (PHQ-9), total score (Kroenke et al., 2001)
Parental stress	Caregivers	Parental Stress Scale, total score (Berry & Jones, 1995)

Health economic outcome measures

- Health-related quality of life of caregivers and adolescents: European Quality of Life 5 Dimensions 5 Level Version (EQ5D-5L) and its proxy version, European Quality of Life 5 Dimensions Youth Version (EQ5D-Y-3L) and its proxy version (Herdman et al., 2011; Wille et al., 2010)
- Capability well-being of caregivers: Oxford CAPabilities questionnaire-Mental Health (OxCAP-MH) (Simon et al., 2018; Vergunst et al., 2017)
- Self-reported resource use and cost measures for caregivers and adolescents PECUNIA Resource Use Measurement (PECUNIA RUM) (PECUNIA Group, 2021; Pokhilenko et al., 2023)

Intervention cost measures

- Facilitator cost form (training & weekly versions)
- Supervisor cost form (training & weekly versions)
- Coordinator cost form

Process evaluation measures

- Attendance registers
- Parenting for Lifelong Health Facilitator Assessment Tool for the Parents and Teens intervention (PLH-FAT-T; Martin et al., 2023)
- Facilitator and supervisor profile questionnaire
- Post-intervention focus group guides for adolescents, caregivers, intervention staff
- Scaling reflections guide
- Readiness assessment checklist

This report focuses on the translation and adaptation of the content of the study measures. Alongside these processes, the FLOURISH consortium also adapted the measures to use on the Open Data Kit (ODK) for digital data collection.

In addition to the measures used to capture the implementation and outcomes of the program that are discussed further in this report, a wide range of other materials were also developed or adapted and translated into Romanian and Macedonian in Phase 1, including:

- Materials providing information on the study:
    - Intervention study information sheets and consent forms for adolescents, caregivers, intervention staff
    - Focus group information sheets and consent forms for adolescents, caregivers, intervention staff
    - Participant recruitment posters
    - Advisory group information for adolescents, caregivers, intervention staff, professional experts
    - Adverse event form and data safety collection protocol
    - Training materials for intervention and research staff

- Materials to collect information for co-production activities to adapt the intervention:
    - Advisory group discussion guides for adolescents, caregivers, intervention staff, professional experts
    - Context mapping interview guides for professional experts
- Intervention materials:
    - Parenting for Lifelong Health (PLH) manual and family workbook
    - Helping Adolescents Thrive (HAT) comics
    - HAT comics discussion guides

2 Methods used for adaptation and translation of study measures

2.1 Intervention and health economic outcome measures

One of the goals of the pilot feasibility study (Phase 1) has been to examine the feasibility and preliminary psychometric performance of the intervention and health economics outcome measures and their translations, using rigorous translation and evaluation procedures prior to the baseline data collection.

For any primary or secondary outcome measures without available official translations, translations were produced following best practices in this area (Reichenheim & Bastos, 2021). For outcome measures with available official translations, such as the Child Behaviour Checklist 6–18 and Youth Self-Report 11–18 (Achenbach & Rescorla, 2001), official translation was used and the translation was checked using steps 2-5 below, as needed.

The following steps were involved in the translation and adaptation of the outcome measures. Steps denoted by ‘a’ were conducted for all intervention outcome measures except for the health economic measures, for which steps denoted by ‘b’ were conducted.

1) A translator with experience in mental health evaluated the acceptability and cultural relevance of the items to the country and culture based on the original (English) version, e.g., whether the item of lack of appetite in Revised Child Anxiety and Depression Scales (RCADS) would be associated with depression in that context.

2a) The same translator translated the English version to Romanian/Macedonian (forward translation).

2b) Two translators performed forward translations of the English version to Romanian/Macedonian languages, with a subsequent forward translation reconciliation (forward translation and forward translation reconciliation).

3) Second translator conducted back-translation to English.

4) One translator compared the translations and assessed concordance and semantic equivalence between the original English version and the back-translations. This involved examining whether the meaning of the concepts in the original instrument was transferred to the translation and will therefore be expected to produce a similar effect among respondents.

5a) The translators met to discuss any issues and discrepancies that emerged and finalized the translations by reaching consensus on any differences.

5a) The translators finalized the translations based on input and feedback obtained from the developer's review for the health economic measures.

6) Translations underwent final proofreading.

This process thus involved three translators fluent in English and the target language for translation (Romanian/Macedonian), two of whom were also required to have experience in mental health topics.

Furthermore, *think-aloud interviews* were conducted after the post-test data collection in December 2023 - January 2024. Ten interviews per country (five with adolescents and five with caregivers) explored item comprehension with adolescents and caregivers in Romanian and Macedonian to facilitate further adaptation of the measures for Phase 2. The interviews covered the primary outcome measures that have not been previously used with adolescents or in the study countries. This included the Revised Child Anxiety and Depression Scales and WHO-5 (World Health Organization – Five Well-Being Index) (Topp et al., 2015; WHO, 1998). Think-aloud interviews also covered the health economic outcome measures that will be used in the optimization and evaluation phases (Phases 2 and 3) and have not been previously used with adolescents or in the study countries: EQ5D-5L and its proxy version, EQ5D-Y-3L and its proxy version, OxCAP-MH, and PECUNIA RUM.

Adaptations of these measures included removal of context-inapplicable parts of resource use measurement and age-appropriate changes in the health economic outcome measures.

Following the delivery of the intervention and post-test data collection in Phase 1, *qualitative focus groups* were conducted. The focus groups primarily focused on the experiences of intervention participation (for adolescents and caregivers) and delivery (for staff). In addition, they included a discussion question for adolescents and caregivers regarding their reflections on the questionnaires, and for staff on the process evaluation and cost measures. In the focus groups, adolescents and caregivers reported that the experience with the data collection was positive. In Moldova, caregivers and adolescents had no specific suggestions about the outcome measures, while in North Macedonia caregivers and adolescents shared a few difficulties and suggestions related to acceptability, e.g., not asking the youngest adolescents aged 10-11 about sexual experience or adapting the wording of the questions. These findings will be integrated into Phase 2 alongside other information on the performance of the measures.

2.2 Intervention cost measures

Specific *intervention cost measure questionnaires* were developed, tested, and adapted in Phase 1. These included forms to capture the time and costs spent by the program facilitators and supervisors (for each group, separate one-off forms for the initial training activities, and weekly forms for ongoing intervention delivery), and the overall delivery time and costs reported by the coordinator at the end of the delivery in the Republic of Moldova and North Macedonia. Information collected in Phases 2 and 3 will serve the basis of the intervention cost estimate for the health economic evaluation, the scalability calculations and will provide additional information for implementation.

The categories for the cost forms were developed between the health economics, process evaluation, and intervention implementation teams to capture all the relevant dimensions required for program delivery. The original draft was also guided by the cost categories used in the evaluation of Parenting for Lifelong Health for Parents

and Teens in Tanzania (Martin et al., 2021). Throughout the process, the forms have been designed and adapted to be suitable in the Republic of Moldova and North Macedonia, e.g., having options for both local currencies and accommodating different start dates for program delivery.

In the post-intervention focus groups, both countries' staff made suggestions for how the intervention cost measures and the processes for collecting these data could be further improved, particularly to reduce the facilitator workload. This feedback, together with the analysis of data from Phase 1, will inform further adaptation to the processes for Phase 2 of the project. In particular, it has been decided that the intervention cost measures need to be assessed in a simpler way to minimize the time required for completion and possible data errors, and a more in-depth completion training will be also provided.

2.3 Process evaluation measures

Process evaluation measures were adapted to the intervention design and implementation. We discuss the translation and adaptation processes below for each measure.

The *Facilitator Assessment Tool* (Revised PLH-FAT-T) was used to assess the fidelity of intervention delivery by the facilitators. The version used is informed by the findings of the study of PLH for Parents and Teens in Tanzania and lessons learned from other PLH studies using the tool, including Preventing child mental health problems through parenting interventions in South Eastern Europe (RISE) study (Martin et al., 2023). The tool was lightly adapted for FLOURISH to suit the context of delivery and the specific goals of the study. For example, a section was added for recording the modifications to the intervention made by the facilitators as one of the goals of FLOURISH process evaluation is to track program modifications.

Attendance registers for caregivers and adolescents were developed for FLOURISH based on the participation modalities in the program. The approach was developed in collaboration between process evaluation and outcome evaluation teams to adapt

the system of attendance data collection to match with IDs for participants used in the pre-post data collection.

The Facilitator and Coach (Supervisor) Profile questionnaires drew on a mix of previously used and new items to capture staff demographics, professional background, and wellbeing. (The word “coach” was replaced with “supervisor” in the names and text of the forms, including in English, to more closely match the corresponding term used in both the Republic of Moldova and North Macedonia.) Several items on professional background that had been used in the evaluation of PLH for Parents and Teens in Tanzania (Martin et al., 2021) were adapted for FLOURISH. To optimize the use of resources and comparability across datasets, the translations for the scales that were used in both the staff questionnaire and the pre-post questionnaire for caregivers, Parental Stress Scale (Berry & Jones, 1995) and WHO-5 Well-Being Index (Topp et al., 2015; WHO, 1998), were used from the outcome measure translation process described above.

Post-intervention focus group guides for adolescents, caregivers, and intervention staff were developed for the FLOURISH study, drawing on the domains of the process evaluation guidance (Moore et al., 2014) and intervention context (Pfadenhauer et al., 2017). The guides were adapted during Phase 1 based on the intervention design and the questions emerging from the feasibility study activities. For example, discussion questions explored the take-up and acceptability of each intervention component.

In addition to this, we adapted a *scaling reflections guide* from a toolkit for supporting adaptive management and documentation of scale up (Expandnet, 2020) and *readiness assessment checklist,* developed by the PLH team for the Parents and Teens intervention.

For the fidelity, attendance, staff profile, focus group, and intervention cost tools, a translator with experience in mental health translated them from English to Romanian or Macedonian. These translations were discussed with the teams from ALTERNATIVA and Health for Youth Association in North Macedonia and the

Republic of Moldova and piloted as part of intervention staff training in both countries. The discussions and piloting resulted in several modifications in cases where the translation was felt to not be equivalent to the original, or not suitable to the terminology used in the given organizational context. The scaling reflections guide and readiness assessment checklist were used in English as these were completed (once) prior to program delivery by the team leaders in North Macedonia and the Republic of Moldova.

3 Summary

A range of measures assessing the outcomes and implementation of the intervention package were developed or adapted for the FLOURISH project and translated into Romanian and Macedonian. For the pre-post outcome measures including the health economic outcome measures, the adaptation and translation processes focused particularly on cultural and linguistic considerations. The details on the performance of the outcome measures in Phase 1 will be reported in forthcoming publications. For the intervention cost measures and the implementation measures, the adaptations were primarily guided by the nature of the intervention and the context of the delivery organizations. The data collected in Phase 1 will inform further adaptations of the measures for Phase 2.

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