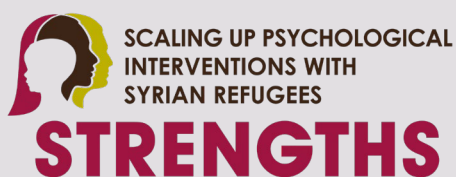# End report on process and outcomes of Step-by-Step implementation in Egypt, Germany, and Sweden

DELIVERABLE 6.3

SCALING UP PSYCHOLOGICAL INTERVENTIONS WITH SYRIAN REFUGEES

STRENGTHS

Project acronym: STRENGTHS

Project title: Fostering responsive mental health systems in the Syrian refugee crisis

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1. Executive summary

1.1. Introduction

This report describes the results of three pragmatic randomized-controlled trials (RCTs) with an online and offline computer- and smartphone-based e-mental health program called Step-by-Step (SbS) for Syrian refugees in Egypt, Germany, and Sweden. It is the final report on the work of Freie Universität Berlin in Work Package 6 (WP6) of the STRENGTHS project.

STRENGTHS (Syrian REfuGees MeNTal HealTH Care Systems) is a European Union Horizon 2020 funded research project that aims to provide and evaluate effective community-based health care implementation strategies to scale-up the delivery and uptake of effective mental health and psychosocial support interventions for Syrian refugees who are in Europe and countries bordering Syria. STRENGTHS is composed of several multi-country studies centred around the implementation of different versions of scalable program to reduce psychological distress.

In addition to the quantitative RCT results, this report also provides the results of the qualitative process evaluation on the implementation of SbS in Egypt, Germany, and Sweden. The report covers key findings up until month 72 of the project.

1.2. Key contributions

One of the defining characteristics of the work done in WP6 of STRENGTHS was that the same digital intervention was evaluated in three different country contexts in parallel and with the same target population. This unique setup took full advantage of the scaling-up potential of digital technologies in mental health care because a single instance of the software (i.e., a single copy of the software, running on a single server) was used by a single team of researchers and helpers based in Germany to provide SbS to participants in Germany, Sweden, and Egypt.

Adaptation and development of SbS
The development of SbS required an interdisciplinary approach to not only develop intervention content that matches the needs of the target population, but also the technological foundation for a secure and robust app that can be used by diverse participants worldwide. This challenging task of user-centred e-mental health development was achieved in close collaboration with the original creators of the SbS intervention approach at the World Health Organization (WHO). Further close collaboration with software developers, designers, creative writers, and voice actors was required to create the final version of SbS. Most importantly, WP6 put a strong focus on user-centred design with immediate participation of Syrians as part of focus groups and key information interviews, as well as part of the team. These efforts have resulted in very high-quality intervention content and a robust software platform, both of which are a solid foundation for future improvements to SbS and its implementation.

Implementation and testing of SbS
Scalability is commonly seen as the key advantage of digital mental health solutions because these solutions are not bound to a location and instead can be used globally via the internet and on mobile devices. The Syrian

refugee crisis provided a unique use case for this approach because Syrians constituted a population with shared experiences and stressors that was distributed over various countries. Consequently, the STRENGTHS project implemented a unique study setup with three separate RCTs that were all using the same IT-infrastructure and helper-team. In a first step, the feasibility and usability of the adapted version of SbS was tested in a pilot study in Germany. Several important improvements were made to improve the usability of the SbS app as well as to optimize the study procedures. Building on this, the three trials in Germany, Sweden and Egypt were conducted that found reductions in psychological distress in the Egypt trial. Due to high intervention drop-out, results within the full sample for Germany and Sweden are limited. However, improvements to psychological distress and partially to functioning among participants in Germany and Sweden were found for participants who did not drop-out and completed the program. Consequently, the trials provided evidence that SbS can be effective, but not all Syrians included profited from the self-help program and many did not complete SbS.

The process evaluation provided further insights into why participant may have stopped using SbS. Overall, the qualitative interviews conducted with study participants showed that most interviewees saw a substantial need for SbS among Syrians, praised the usability, reliability and security of the system and reported positive outcomes of using the program. At the same time, important barriers to accessing SbS and to user engagement (i.e., factors that encourage participants to continue using the app) were identified. Major findings were that some wished for further support, including in-person contact with a specialist. Others found the content not relevant enough for the fast-changing life circumstances of Syrians living and integrating in Germany and Sweden. Participants provided extensive feedback and suggestions to improve SbS, resulting in important conclusions, such as that digital interventions like SbS require an established trust base for implementation (e.g., through trusted NGOs or social media influencers and that the app requires additional measures to tailor intervention content to user needs to improve engagement.

In summary, the findings show that SbS can be a helpful and highly scalable approach that can significantly improve psychological distress and functioning for parts of the Syrian population in host countries. At the same time the findings underline the importance of embedding digital mental health solutions like SbS within existing healthcare structures to provide referral options for those who do not profit from a digital self-help program alone. Due to its robust technological framework and its unique characteristics as an anonymous, secure, and easy-to-access offer, SbS is equipped to reach a large number of users and can therefore be seen as an early offer within a coordinated, stepped health care approach.

Scientific outputs

Through the STRENGTHS project, WP6 has contributed to the field of user-centred e-mental health development for refugee populations (Burchert et al., 2019) as well as to the topic scaling-up this approach in diverse health care systems (paper under review). Further publications on the clinical effects in Germany, Sweden and Egypt, the process evaluation and the development of the adaptable e-mental health intervention software developed as part of STRENGTHS are currently in preparation.

2. Definitive RCTs in Egypt, Germany, and Sweden

2.1. Background and preparatory work

2.1.1. Description of context in which studies took place

The Egyptian context
The need to strengthen mental health systems globally, but especially in low- and middle-income countries (LMICs) like Egypt has increasingly become the focus of international efforts to scale-up mental health services (Petersen et al., 2011). At the start of STRENGTHS, the impact of the Syrian refugee crisis on Egypt was not as well documented and internationally recognized as in other receiving countries. Access to primary health care was granted but the health system was not prepared for the additional burden, the quality of the treatment was poor and specialized health services were expensive (UNHCR, 2017). As a low- and medium income country, Egypt faces socioeconomic challenges that leave refugees particularly vulnerable to poverty and insecure food supply. Changes in Egypt's political climate have reportedly led to an increase in restrictions and discrimination of Syrian refugees (Refugee Council USA, 2015). At the same time, the work of humanitarian organizations in Egypt is impaired by a restrictive legal framework in which NGOs are severely limited regarding local operation and international cooperation (ICNL, 2016). A lack of funding for UNHCR in Egypt has further caused cutbacks in external health assistance effectively limiting it to the most vulnerable groups of refugees (UNHCR, 2017). These factors still negatively affect the responsiveness of the Egyptian health system which leads to a larger treatment gap.

Egypt was chosen as one of the implementation countries for SbS in STRENGTHS because its health system was not able to provide basic mental health care to Syrian refugees while at the same time interventions with personnel on site had become increasingly difficult leading to a growing mental health treatment gap. However, through an established cooperation with Caritas in Egypt, access to the Syrian population in Egypt was still possible and a low-threshold unguided digital intervention like SbS was therefore one of the few interventions considered to be feasible for offering support at a larger scale to Syrian refugees in Egypt without the requirement of establishing additional local structures.

The German context
While the German health system offers general and specialized health care for refugees and asylum seekers, access to adequate mental healthcare provision is often limited in practice (Bozorgmehr et al., 2016; Langlois et al., 2016). Barriers to delivery and uptake of mental health interventions for refugees are multifaceted. They include the language barrier in combination with limited coverage of interpreter costs, culture-related barriers, a lack of trained personnel, geographical distance to intervention sites and legal restrictions (Böttche et al., 2016; Norredam et al., 2006). Refugees have only limited access to mental health care during the first 15 months after arrival in Germany. During this period, mental health care is provided by psychosocial organizations, where there can often be long waiting times (Baron and Flory, 2016). Emergency care is available from hospitals where required. However, the lengthy and often complex specialized treatments preclude simple access for refugees who are often unable to attend regular treatments over extended periods of time and must move frequently between asylum locations. Consequently, even if Syrian refugees in Germany get access to care there is a lack of mental health programs adapted to the local Syrian language, culture and the needs and requirements of the Syrian refugee population.

Germany was chosen as one of the implementation countries for SbS in STRENGTHS because it has received the largest absolute number of Syrian refugees in Europe and encounters a severe lack of qualified personnel to provide adequate care for Syrian refugees in Arabic. SbS – a fully translated and culturally adapted self-help program in Arabic – was therefore seen as a promising low-threshold offer for Syrians in Germany.

The Swedish context

Like Germany, the Swedish health system offers general and specialized health care for refugees and asylum seekers and therefore encounters similar problems. By law, asylum seekers are entitled to a voluntary health assessment and to "health care that cannot be postponed". However, due to structural limitations these health assessments often fail to identify health care needs, especially those that are psychological in nature (Pacheco et al., 2016). Consequently, the opportunity to refer persons in need to appropriate mental health care is often missed. In addition, due to a lack of interpreters, Swedish health professionals face practical challenges when treating clients from Syria (Hunter, 2016). Sweden has taken digital measures to improve migrant integration by supporting the smartphone apps that provides support with social integration, employment, housing, language, and education. Sweden is also one of the leading countries worldwide in digital healthcare service implementation and has adopted several e-health services as part of the general health system (Hägglund and Koch, 2015).

Sweden was chosen as one of the implementation countries for the Step-by-Step in STRENGTHS because it has received the largest per capita number of refugees of all European host countries and encounters a severe lack of mental health care providers who can offer assistance in Arabic. At the same time, Sweden has a history of accepting digital innovations as part of the health system which increases the likelihood that SbS will be supported and adopted by local providers. A digital mental health self-help tool like SbS was considered a potentially useful addition to existing digital tools in Sweden that have a stronger focus on social work topics.

2.1.2.   Description of Step-by-Step

Theoretical background

SbS is a potentially scalable e-mental health intervention approach developed by the WHO for adversity-affected populations (Carswell et al., 2018). SbS utilizes evidence-based cognitive behavioural techniques including behavioural activation, psychoeducation, stress management, increasing social support, positive self-talk, and relapse prevention.

Content

The self-help intervention consists of 5 weekly sessions that tell a continuous story through illustrated educative narratives. Within these narratives, interactive exercises (e.g., breathing exercise for stress management; activity planner for behavioural activation) are embedded. Figure 1 provides an overview of key sections of the app. Users are instructed to plan and practice these between sessions. All texts are available in Levantine Arabic dialect and in English. The app is fully audio supported for illiterate users. The illustrations and Arabic texts were culturally adapted for Syrian, Lebanese, and Palestinian populations. The content of Step-by-Step was developed with experts in psychological care, e-mental health, and global mental health. It has gone through extensive peer-review, with over 30 external experts reviewing the intervention.

Guidance model

In STRENGTHS, the original WHO approach for providing SbS was adapted for fully self-guided administration to maximize the scalability of the intervention. In this version of SbS, contact was provided on-demand by trained and supervised non-specialist research assistants called "e-helpers", using the in-app messaging system. The e-helper team was located in Berlin, Germany. It consisted of Syrian Arabic-native speakers with a background in psychology or social care and were trained as well as supervised by experienced mental health practitioners using specifically developed training materials. E-helpers operated within the standardized framework of a decision tree expert system. Topics not covered by this system are forwarded to the clinical supervisor. The guidance model was described in more detail in STRENGTHS Deliverable 6.2.

Figure 1. *Sections of the SbS mobile app version*
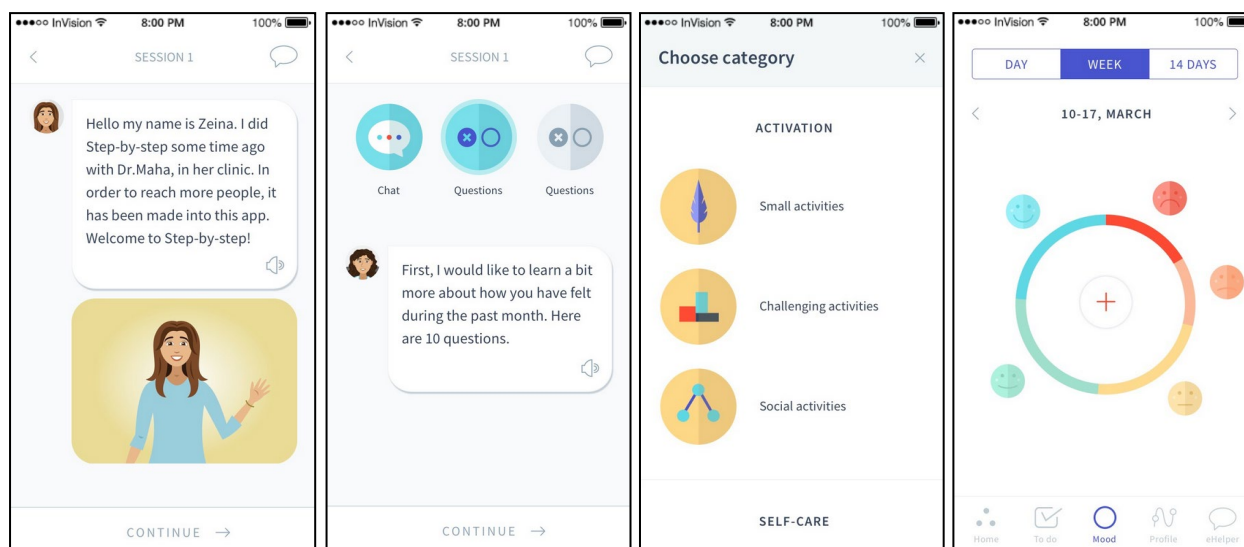
Delivery model

The intervention was available in the form of a mobile app for iOS and Android as well as in the form of a mobile-optimized website for use with standard web browsers on mobile devices, laptops, and desktop computers. The app versions were available for download directly from the Google Play Store or the Apple App Store and had extensive offline capabilities. They therefore were available to users without stable access to the internet.

Data protection

The software was developed, hosted, and maintained in Germany following German as well as European data protection laws including the EU General Data Protection Regulation (GDPR). All personal data was and is handled strictly confidential. Furthermore, appropriate technical, physical, and organizational measures were implemented to ensure the security of personal data. These measures include protection against accidental or unlawful destruction, accidental loss, or alteration, unauthorized or unlawful storage, processing, access, or disclosure. The processing of personal data and the measures to ensure data security are documented in a written security policy.

2.1.3.   Cultural and contextual adaptation of Step-by-Step

User-centred approach

Prior to conducting the pragmatic trials in Egypt, Germany and Sweden, the STRENGTHS version of SbS was carefully adapted to the local contexts using an iterative, user-centred approach based on formative research methodology. The process and results have been published (Burchert et al., 2019). At this stage of the project, 128 adult Syrian refugees residing in Germany, Sweden and Egypt took part in qualitative interviews and focus groups. A range of outcomes was assessed, including access to and usage of digital technologies, potential barriers regarding the use of such technologies and preferences when it comes to the design of digital technologies for the population. Based on these findings, interactive prototypes of the app were created, and feedback was gathered regarding usability, user experience and potential strategies for dissemination.

Key adjustments after pilot study

Enhanced narratives

The initial version of the narrative content of the app consisted of story sections with one narrator each. In addition, there was only one version of the story per gender (male and female). Users of the app perceived this as not very dynamic or engaging. Especially younger users did not perceive the given story as very relevant

to their lives. The revised version of the stories introduced narratives in which several protagonists interacted with each other. Furthermore, one new story was created per gender that focussed on a younger protagonist.

Overlay tutorials
In the first version of the SbS app, the functionality of new interactive exercises was explained in narratives prior to unlocking an exercise for the first time. Tests indicated that these instructions did not provide enough guidance. To improve the user experience, it was decided to make instructions available at any time when doing an exercise. Therefore, a series of tutorials was created and added in the form of a tutorial button to the exercises to provide users with an easy way of accessing instructions whenever needed.

Mood graphs and diary
The mood tracking component of the app was introduced to point out a key therapeutic component of the Step-by-Step intervention: Being active on a regular basis can have a positive effect on depression and low mood. However, the initial implementation of the feature did not illustrate this connection sufficiently throughout the intervention. Therefore, additional mood summary graphs (7 days and 14 days) as well as a diary component were implemented. The diary allowed the addition of current activities to mood ratings to further underline the association of activities and mood while the mood graphs provide access to individual mood trajectories and encouragement to track mood regularly.

My Journey feature
To further improve engagement, the My Journey feature was developed to provide a comprehensive summary of all activities and the intervention progress. Under the My Journey Tab, app users had access to their daily mood average, all diary entries, the number of scheduled and completed activities and the completed Step-by-Step sessions.

2.1.4.   Pilot randomized controlled trial in Germany

Recruitment
Prior to starting the definitive RCTs, the app was piloted with a smaller sample in Germany to identify any issues that may have been overlooked at previous stages of testing. At the pilot stage, the recruitment was exclusively conducted on the social media platform Facebook. To this end, information on the study was posted in popular Facebook groups for Syrians. In addition, paid Facebook ads were used to reach Syrians in Germany. Between December 2019 and the end of January 2020, a total of 89 eligible participants were included. At this stage, the social media recruitment was stopped, and 13 additional participants joined until June 2020, when the study was closed. Based on the pilot study, it was concluded that a social media recruitment strategy will be a feasible approach to reaching the required sample size in the definitive trials.

Results
Findings from the pilot trial in Germany that was conducted during this reporting period, are limited due to low statistical power caused by the small sample size and high dropout rate. Qualitative assessments indicated that the Step-by-Step intervention itself was acceptable and may be feasible when adjusting the download size of the app, the length of the initial assessments and the way in which the e-helper model is explained. Participants indicated that the audio files increased the app's size in devices to an extent that may prevent users from downloading the software. In addition, participants pointed out the length of the baseline assessment as a major limitation due to the high commitment required of participants at an early stage (i.e., before having access to the intervention). This was reflected in high non-start attrition. The main findings from the pilot study are the three usability issues listed above, which were addressed prior to starting the definitive trials.

2.1.5.   Ethics approval definitive RCTs

Participant safety
SbS is a low-intensity self-help intervention for Syrian refugees with increased psychological distress and reduced functioning. Prior to participation, applicants were screened for plans to end their life. If a user confirmed this, he or she was not included in the study and was instead immediately provided with general self-care tips as well as with details of services in the country of residence. The intervention is based on evidence-based therapeutic techniques that have been found to be safe for use in a range of populations and the content has been rigorously tested in interviews and focus groups with the target population, therefore it was considered unlikely that distress will arise as a result of using the app. However, the team anticipated risk from the fact that the participants were refugees and – as members of this population – were at risk of crisis or worsening of symptoms due to stressful or traumatic experiences in the past, due to information of a personal or political nature that are related to family members, friends or the situation in Syria or the host country in general as well as due to other forms of post-migration stressors. To address this, users of the app were asked to regularly answer a short symptom screening questionnaire as well as to track their mood within the app. Based on this data, worsening of symptoms were detected and users with such a pattern were encouraged to seek additional help.

Ethics approvals
Due to its cross-border nature, the studies in WP6 were extensively reviewed by several local ethical review authorities and by the WHO. Table 1 provides an overview on all ethical approvals acquired by WP6 for the STRENGTHS definitive RCTs in Egypt, Germany, and Sweden.

Table 1. *Overview on ethical approvals*

	Ethical review authority	Application ID	Date of ethical approval
Germany	Freie Universität Berlin Ethical Review Board (Ethikkommission)	161/2017	Aug 16th 2017
		161/2017 (amendment)	Jan 23rd 2020
Egypt	The American University in Cairo Institutional Review Board	2020-2021-009	Oct 10th 2020
Sweden	Swedish Ethical Review Authority (Etikprövningsmyndigheten)	2020-00261	Apr 8th 2020
WHO	Research Ethics Review Committee (WHO ERC)	ERC.0003321	Feb 2nd 2020

2.1.6.   Objectives and design

Study design
For each of the three trials, a single-blind, randomized, two-arm control group-design was applied. Participants were allocated to one of two conditions using a block randomization algorithm. Participants in both groups answered sets of questionnaires at the beginning of the study (T1 / baseline), 6 weeks after starting the study (T2 / post), 4.5 months after starting the study (T3 / follow-up 1) and 12 months after starting the study (T4 / follow-up 2).

Main objective
The main hypothesis in WP6 was that the adapted contact-on-demand version of SbS will decrease symptoms of psychological distress as compared to a care-as-usual (CAU) control group. Therefore, the main objective was to test the effectiveness of SbS + CAU compared to CAU only.

Secondary objectives
To establish the robustness of the findings and the scalability of the digital approach, WP6 aimed at evaluating SbS in three different country contexts simultaneously. In all three RCTs, secondary outcomes comprised of

symptoms of PTSD, functional impairment, and self-identified problems. In addition, it was the aim to evaluate the process of SbS provision in all three countries, to identify barriers for seeking and receiving care as well as bottlenecks in providing Syrian refugees with mental health care. By these means, the work package aimed at identifying ways of improving the program and ways of scaling up SbS in the respective health care systems of the implementation countries.

2.2. Methods

2.2.1.   Participants and procedures

Inclusion criteria
To be eligible to participate in the trial, a subject had to meet all the following criteria: Syrian displaced person (based on self-disclosure) with Arabic-speaking with a basic level of literacy. Participants had to show elevated levels of psychological distress (K10 > 15) and/or reduced psychosocial functioning (WHODAS 2.0 > 16) and were required to have access to an iOS or Android smartphone/tablet or a computer/laptop with internet connectivity.

Exclusion criteria
A potential participant who meets any of the following criteria will be excluded from participation in this study: People who have plans to end their life and minors under the age of 18.

Sample size
Power calculations suggested a minimum sample size of 266 participants per group based on an anticipated effect size of 0.4 (power = 0.90, a = 0.05, two-sided) and considering a drop-out at the 3-months follow-up (primary outcome) of approximately 50%. Consequently, a total of N =532 participants were the recruitment goal in each of the trial countries. Table 2 provides an overview of the recruited sample in each of the study locations.

Recruitment
The recruitment in Germany and Sweden began in August 2020 and stopped in January 2022. For Egypt, recruitment ran from March 2021 to July 2021. The recruitment was mainly done through social media outreach in the German and Swedish trials, foremost through ads on the official SbS pages on Facebook and Instagram, and later through a paid influencer campaign with 12 well-known Arabic influencers. In Alexandria, Egypt, an NGO was engaged in recruiting for the Egyptian trial due to its local expertise. The NGO team contacted participants personally and invited them to participate after providing information about the study. Interested individuals could access the app or the web version of SbS directly through posts on social media or on-site with the NGO team's assistance.

Study procedures
Once downloaded or accessed via a web browser, the app provided study information, data protection information and a consent form. Those willing to participate then created an account by picking a username and setting a secure password. Afterwards, participants completed the screening questionnaires. Participants not matching the inclusion criteria (see above) received a thanking and an explanatory message clarifying that they could not participate now. Also, candidates at imminent suicide risk received a message with contact information for emergency services in the respective country and instructions to contact these services. Upon meeting the inclusion criteria, participants were asked to provide contact information (i.e., phone number or email address) so they could be reminded when post and follow-up assessments were due. Randomization used a permuted block design and was conducted individually at a 1:1 ratio.

Table 2. *Demographic characteristics of study participants per country*

Characteristics	Egypt (n = 538)	Germany (n = 559)	Sweden (n = 184)
Age, *M (SD)*	33.6 (10.9)	30.7 (8.2)	32.8 (10.0)
Age range	[18-71]	[18-62]	[18-70]
Sex, % (*n*)			
Female	67.3% (362)	69.6% (389)	80.4 (148)
Marital status, % (*n*)			
Never married	20.0% (108)	31.1% (174)	20.6% (38)
Married	67.3% (362)	53.1% (297)	65.8% (121)
Separated	4.0% (22)	5.2% (29)	3.3% (6)
Divorced	4.3% (23)	6.6% (37)	6.5% (12)
Widowed	3.3% (18)	0.5% (3)	0.0% (0)
Cohabiting	0.6% (3)	2.9% (16)	3.8% (7)
Not provided	0.4% (2)	0.5% (3)	0.0% (0)
Education, % (*n*)			
No education	7.0% (38)	1.4% (8)	1.6% (3)
Elementary	31.8% (171)	4.7% (26)	6.5% (12)
Secondary	44.2% (238)	39.4% (220)	35.9% (66)
University	11.7% (63)	45.4% (254)	47.3% (87)
Technical	3.5% (19)	8.6% (48)	8.7% (16)
Not provided	1.7% (9)	0.5% (3)	0.0% (0)
Work permit, % (*n*)	38.1% (205)	86.6% (484)	94.0% (173)
Occupational status, % (*n*)			
Paid work	18.9% (102)	25.0% (140)	34.2% (63)
Unpaid work	0.6% (3)	0.4% (2)	0.0% (0)
Self-employed	11.9% (64)	5.9% (33)	2.2% (4)
Student	8.2% (44)	30.6% (171)	33.7% (62)
Unemployed (e.g., homemaker)	55.2% (297)	33.6% (188)	22.3% (41)
Other	3.9% (21)	3.8% (21)	6.5% (12)
Not provided	1.3% (7)	0.7% (4)	1.0% (2)

2.2.2.   Measures

Method of assessment

All assessments were fully automatized (i.e., there was no personal contact that would have required blinding of assessors) and conducted through electronic questionnaires directly within the SbS app. All question texts and answer options were provided with optional audio support to assist participants with lower literacy.

Overview of assessments

Assessments were conducted at the following time points (see Table 3 for details):

T0 = Screening assessment (immediately after registration)

T1 = Baseline assessment (immediately after T0)

TI = Weekly intermediate assessment (after 1,2,3,4, and 5 weeks)

TC = Completion assessment (after completion of Step-by-Step session 5)

T2 = Post assessment (6 weeks after T0)

T3 = 3-month follow-up assessment (3 months after T2)

T4 = 12-month follow-up assessment (12 months after T1)

Table 3. Overview of assessment instruments

Construct	T0	T1	TI	TC	T2	T3	T4
Demographics		Demographic questions			Demographic questions (selected items)	Demographic questions (selected items)	Demographic questions (selected items)
Suicidality risk assessment	Suicidality screening						
Psychological distress	K10		K10	K10			
		HSCL-25		HSCL-25	HSCL-25	HSCL-25 (primary outcome)	HSCL-25
Functioning	WHODAS			WHODAS	WHODAS	WHODAS	WHODAS
PTSD		PCL-5 (short)			PCL-5 (short)	PCL-5 (short)	PCL-5 (short)
Self-defined problems		PSYCHLOPS			PSYCHLOPS	PSYCHLOPS	PSYCHLOPS
Post-migration stressors		PMLD				PMLD	PMLD
Access to health services		Access to care questionnaire					
Cost of care		Cost questionnaire			Cost questionnaire	Cost questionnaire	Cost questionnaire
User satisfaction					CSQ-I		

Primary outcome

The Hopkins Symptoms Checklist (HSCL-25)

The instrument consists of 25 items related to psychological distress (Mollica et al., 1987). The items are rated on a 4-point Likert scale. The Arabic version of HSCL-25 has been used in various studies (Al-Turkait et al., 2011; Caspi et al., 2008; Kobeissi et al., 2012; Selmo et al., 2016). In addition, the measure has been used in studies on the effectiveness of lay-counsellor delivered, transdiagnostic, psychological interventions (Murray et al., 2014) and in traumatized refugees in Norway, where the HSCL-25 correlated highly with other measures of mental health (Lavik et al., 1999).

Secondary outcomes

The WHO Disability Assessment Schedule 2.0 (WHODAS 2.0)

WHODAS is a generic assessment instrument assessing health and disability (WHO, 2010). It is simple to administer and applicable across cultures and can be used in all adult populations. The WHODAS covers six domains (cognition, mobility, self-care, getting along, life activities, participation). It assesses difficulties people have due to their illness across these domains during the last 30 days. Difficulties are scored on a five-point Likert scale ranging from 0 (none) to 4 (extreme), before summation (range 0-48). Higher scores indicate worse functional impairment.

The PTSD Checklist for DSM-5 short version (PCL-5 short)

The instrument assesses symptoms during the past week according to the DSM-5 PTSD diagnosis. In the study an 9-item short version of the original 20-item scale (Weathers et al., 2013) was used. The short form covers all diagnostic criteria of the DSM-5 PTSD diagnosis (re-experiencing, avoidance, negative thoughts or feelings and trauma-related arousal and reactivity). The short form was found to be highly correlated with the full 20-item version (Price et al., 2016). Items are rated on a 0-4 scale, with higher scores indicating worse symptomatology.

The Psychological Outcomes Profiles Scale (PSYCHLOPS)

As an indicator of personalized intervention outcome, the Psychological Outcomes Profiles (PSYCHLOPS) was assessed (Ashworth, 2007). PSYCHLOPS consists of two questions on self-defined problems that participants encounter in their daily lives. Two additional questions assess functioning (i.e., how much the problems affect daily activities) and general wellbeing. The questions are rated on a 0-5 Likert scale.

Covariates
Demographic variables
Key characteristics of the study population were assessed using single item questions on sex, age, education, marital status, and occupational status.

The Post-Migration Living Difficulties Checklist (PMLD)
Post-migration stressors were assessed using the PMLD (Silove et al., 1997; Steel et al., 1999). This 17-item scale examines the extent to which post-migration challenges had been of concern to the individual over the past 12 months. Items are rated on a five-point scale, ranging from 0 (not a problem) to 4 (a very serious problem). Items scored at least 3 (a serious problem) are considered positive responses, yielding a total count of living difficulties. The 17-item adapted version of the scale used in this study has consistently been identified as a predictor of mental health among displaced populations (Nickerson et al., 2010; Schweitzer et al., 2006; Steel et al., 2006, 2006) and has previously been used in Arabic speaking refugees (Nickerson et al., 2015; Schick et al., 2016).

Questions for other partners in STRENGTHS
Access to health services and cost of care
Perceived access to health services were measured through a questionnaire that was developed by the London School for Hygiene and Tropical Medicine (LSHTM) for the STRENGTHS studies. The data was shared with STRENGTHS WP2 for analyses. In addition, an adapted version of the Service Receipt Inventory (SRI) (Chisholm et al., 2000) was developed for the collection of data on service utilization and related characteristics of people with mental disorders, as the basis for calculating the costs of care for mental health cost-effectiveness research. The questionnaire assesses the frequency and intensity of service use, so that service costs can be calculated as part of STRENGTHS WP7.

2.2.3.   Interventions (SbS and CAU) and trainings

Control condition (CAU)
The control group received one short session with basic psychoeducation and information on available services (CAU) in their country. In a separate section of the SbS app participants had access to a structured list of types of offers and contact addresses. The wording of the psychoeducational texts in the CAU-session was identical to that in the first session of SbS to ensure comparability. However, it was presented without introducing the story narrators and illustrations (see below). This group could utilize other health services.

Intervention condition (SbS + CAU)
The SbS app encompasses five brief sessions (30 min, respectively), each designed to illustrate and teach various skills and practices. Therapeutic strategies included psychoeducation and performing small and enjoyable activities (session 1), behavioural activation (session 2), stress management (session 3), reaching out for social support (session 4), and positive self-verbalization and relapse prevention (session 5). Intervention content was delivered through a narrative with interactive exercises that allow users to apply the techniques introduced throughout the stories in their own lives. The narrative had a female and a male version, with two versions each for married individuals with children and unmarried individuals. Participants were able to choose the protagonist's appearance (i.e., a service recipient), widely representing the primary cultural groups. The story also featured a clinician (i.e., a service provider).

Moreover, all SbS content was provided as audio recordings to facilitate the usage for specific groups (e.g., older people with visual problems or illiterates). The intervention group received full access to the app, including an introduction session (15 min), five weekly sessions, a digital mood tracker, and a calendar function. Following the contact-on-demand approach and via a built-in messaging system or email, app users could ask e-helpers for help regarding questions about the study, the app, or technical issues. They also

received the CAU elements outlined above. Participants in the intervention group could use other healthcare services simultaneously.

E-helper training
Due to the non-specialist character of the e-helpers, a systematic training was required. The training was developed and provided by clinical experts and experts in e-mental health. It was mandatory before working with participants. The e-helper training developed as part of the STRENGTHS project consisted of five days in person training and two additional days of at home training. The protocols equipped prospective e-helpers with the knowledge and tools they needed for their role as e-helpers. This included learning about: (1) The overall intervention, (2) the definition of roles and responsibilities of e-helpers, (3) the process of providing contact-on-demand to users and (4) protocols for dealing with problem situations that might arise. The detailed training curriculum and more in-depth information on the training was provided in STRENGTHS Deliverable 6.2.

2.2.4.   Analyses

ITT analyses
Primary data-analyses for all trials were conducted with the full intention-to-treat (ITT) datasets, including all participants that completed the baseline assessment and that were randomized to one of the study conditions. The main analyses were conducted in R version 4.1.3 using linear mixed models to estimate treatment effects at the 3-month follow-up assessment (primary endpoint). The model was specified with study condition as fixed effect, dummy variables for the post and follow-up timepoints as well as the two corresponding interaction terms of condition with time, and a random effect for the individual participant. This model was used to estimate the effect of the study condition at post and follow-up on symptoms of psychological distress (primary outcome) as represented by the regression coefficients of the two condition*time interaction terms. This model was also applied to estimate the effects of study condition on the secondary outcome measures (functioning, symptoms of PTSD and self-defined problems). Cohen's d (d) as the indicator for effect size was calculated by dividing the mean difference between conditions at a timepoint by the combined standard deviation (SD) of both conditions at that timepoint. For all analyses, two-tailed tests were applied with $p < .05$ as indicator of statistical significance.

PP analyses
Additional exploratory per protocol (PP) analyses were conducted using only data of intervention completers, i.e., data of study participants in the intervention condition that completed the first 4 out of 5 SbS sessions and data of control group completers, i.e., data of participants who completed the CAU information session.

2.3. Sample

2.3.1. Flow of participants

Flowchart

Figure 2 shows the participant flow in all three trials. The recruitment goal for participants randomized was reached in Egypt and Germany. In Sweden, the target sample size was not reached. In all three countries, initial drop-out after creating an account in the SbS app was high, mainly due to baseline assessment non-completion. The most common cause of study exclusion at the screening stage was indication of suicidality. These participants were referred to alternative offers in their respective countries.

Figure 2. Participant flow
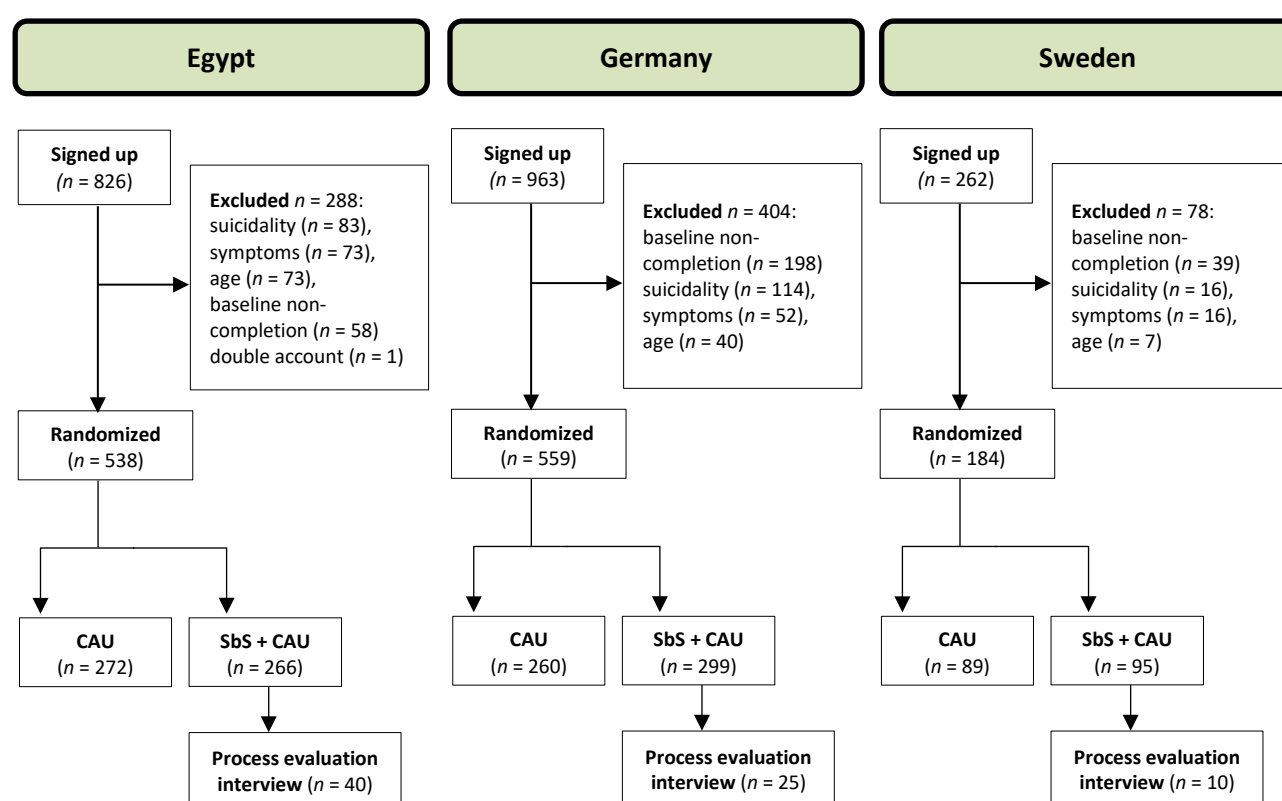
Study and intervention adherence

Table 4 provides more in-depth findings on the number of participants who completed sections of the intervention and the study assessments. Overall, the studies had high non-start attrition ranging from 5% in Germany to 8% in Egypt and Sweden. Non-start attrition occurs after completion of the baseline assessment, before participants start with the SbS intervention. Initial drop-out rates at the introduction stage of the intervention were high as well with a completion rate of the introduction between 79% (Egypt) and 63% (Germany). Throughout the intervention, drop-out rates increased from session to session in all three countries. In Egypt the completion rates were generally higher with 37% of the participants reaching intervention completion (i.e., completion of at least 4 out of 5 SbS sessions). Intervention completion was substantially lower in Germany (13%) and Sweden (18%).

Table 4. In-depth Overview of Participants' Flow and Study and Intervention Adherence

	Number (*n*) and percentage of participants per country					
	Egypt		Germany		Sweden	
Completed onboarding and baseline assessment	**538**	**(100%)**	**559**	**(100%)**	**184**	**(100%)**
Intervention group	**266**	**(100%)**	**299**	**(100%)**	**95**	**(100%)**
Completed session 1	177	(67%)	100	(33%)	39	(41%)
Completed session 2	133	(50%)	57	(19%)	30	(32%)
Completed session 3	102	(38%)	49	(16%)	17	(18%)
Completed session 4	98	(37%)	40	(13%)	17	(18%)
Completed session 5	68	(26%)	31	(10%)	12	(11%)
Control group	**272**	**(100%)**	**260**	**(100%)**	**89**	**(100%)**
Started information session	232	(85%)	239	(92%)	77	(87%)
Completed information session	207	(76%)	198	(76%)	66	(74%)
Completed post-assessment	**393**	**(73%)**	**214**	**(38%)**	**68**	**(37%)**
Completed follow-up-assessment	**344**	**(64%)**	**172**	**(31%)**	**47**	**(26%)**
Non-start attrition (intervention group)						
Fulfilled inclusion criteria	**266**	**(100%)**	**299**	**(100%)**	**95**	**(100%)**
Started introduction	245	(92%)	284	(95%)	87	(92%)
Completed introduction	209	(79%)	189	(63%)	62	(65%)
Started session 1	202	(76%)	167	(56%)	51	(54%)

2.4. Findings and conclusions

2.4.1. Adherence

Sample characteristics

Consistent with most digital interventions (Karyotaki et al., 2015), the percentage of female participants in the three trials was higher than the percentage of male participants. Additionally, in all but Egypt, higher-educated participants were more represented, which is also often the case in digital interventions targeting (Kayrouz et al., 2018). The country samples also differed in employment status. In Sweden, the majority with approximately 80% of the sample was employed or in training/education. The employment rate among participants in Germany was slightly lower with 70%. The Egypt sample on the other hand had a substantially higher unemployment rate of 55%.

Recruitment, study, and intervention adherence

With a recruitment goal of N = 532 participants, study recruitment for the three separate trials was successful in Germany and Egypt while the recruitment goal was not reached in Sweden (35% of the required sample). In terms of study adherence (i.e., completion of assessments), the Egyptian trial performed better than expected with a completion rate of 63% at the 3-month follow-up. The expected 50% completion rate at the primary outcome time point was not reached in Germany (31%) and Sweden (26%). Intervention adherence (i.e., completion of intervention sessions) was also lower than expected with 37% intervention completion (i.e., completion of at least 4 sessions) in Egypt, 18% in Sweden and 13% in Germany. Here as well, adherence was significantly better in Egypt, compared to the other trials. Low retention rates are a common problem in low-threshold smartphone-delivered interventions (Linardon and Fuller-Tyszkiewicz, 2020), especially if the intervention is unguided (Musiat et al., 2022). To a lesser degree, the control condition in all three countries was affected by attrition as well. As part of the CAU condition, participants received a short information

session to inform about CAU in the respective country. This session was completed by approximately three-quarters of the study participants in all three countries.

2.4.2.   Barriers to recruitment

Recruitment for the trial in Egypt started in March 2021 and was completed within 4.5 months. For Egypt, the WP6 team worked closely with an NGO responsible for Syrian refugees in the Alexandria region. For recruitment, local staff was subcontracted to approach potential participants directly by phone. The staff was trained to inform participants about the study and to provide basic assistance with accessing the app. In close cooperation with the WP6 team, safe recruitment strategies during the pandemic and approaches to support participants in case of adverse events were developed and implemented. This recruitment strategy proved to be highly effective.

In Germany and Sweden, recruitment efforts encountered several barriers that made reaching the required sample sizes challenging. In addition to social media recruitment, WP6 reached out to different organizations involved in social and mental health services for Syrian refugees. The goal was to build up strong collaborations and direct channels of communication to promote Step-by-Step. These organizations covered clinical settings (e.g., trauma center for refugees, therapeutic institutions for refugees), NGOs, governmental institutions (e.g., administration, job placement agencies), welfare organizations and refugee accommodation organizations. In a series of workshops and information events, the WP6 team provided presentations to these groups of stakeholders to share information and discuss the approach with interested parties. In addition, information materials in the form of flyers and summaries for decision makers were created and shared in digital and paper format. Despite these efforts, recruitment was slow for most of the recruitment period. As a main factor, the COVID-19 pandemic was identified to substantially affect the needs of the Syrian community and the effectiveness of social media recruitment. In addition, lockdown measures made it significantly harder to reach potential participants through pathways that require personal contact (e.g., at help organizations, language schools, doctor's offices, or government offices). This severely undermined the effectiveness of stakeholder-based recruitment approaches.

With the second wave of COVID-19 in Germany in the autumn of 2020, WP6 adjusted the recruitment strategies and extended the new approach to Sweden. The team subcontracted an advertisement agency with a focus on ethno-marketing to produce videos as additional promotional material and to coordinate a Facebook recruitment campaign with in-depth tailoring to the Syrian community in Germany. Eventually, WP6 collaborated with Syrian social media influencers to create a tailored mental health campaign with social media content to be shared by the influencers on their channels. This campaign was successful in reaching many potential participants and resulted in the recruitment target for Germany to be achieved. The approach also substantially increased recruitment numbers in Sweden towards the end of the recruitment period.

2.4.3.   Limitations

As a global factor, the COVID-19 pandemic may have had a stronger, superimposed impact on participant's mental health, daily stressors, and overall detrimental effects on the economic and health situation of study participants. Large parts of the data collection were conduced during different stages of the pandemic. This may have introduced a systematic effect that e.g., could have increased drop-out due to other pressing matters or reduce effects of the intervention due to pandemic-related symptom deterioration.

At the same time, digital interventions such as SbS gained in relevance because of the pandemic. Lockdowns and stronger limitations to attending mental health services in person rendered digital approaches a viable alternative, which may have been an effect in the Syrian sample as well. This may have led more positive recruitment results than would have been the case otherwise. However, there we no spikes in recruitment observed throughout the pandemic that were in any way associated with e.g., the tightening of measures by

the government. Given that recruitment rates were higher during the Germany pilot study, which was conducted prior to the pandemic, there is no strong indication that the pandemic resulted in a higher interest in SbS among Syrians.

Finally, SbS was not tested against a waitlist control group but against a care-as-usual control group that also received basic information in a session withing the app. While this control condition was designed to be of information value only, it also contained encouragement to seek out available care-as-usual offers and provided a country-specific list of resources. Given a strong effect over time in both conditions, there may have been an effect of the control group content that reduced the between group effect sizes.

2.4.4.   Conclusions

The three separate trials on SbS in Germany, Sweden and Egypt provided valuable insights into the implementation of a digital self-help intervention for Syrians in diverse settings. Key findings of the trials are:

Recruitment is built on trust
In Germany and Sweden, recruitment for the studies proved to be a challenge. The research team tried a variety of different approaches, but the only efficient approach was working with social media influencers who had access to a community that trusted them. The same was found in Egypt where participants were contacted by a trusted NGO with which they already had an established relationship of receiving aid. These findings underline that the dissemination of SbS requires a sustainable basis of trust and that dissemination cannot only rely on social media, poster, flyers, or other forms of traditional media campaigns.

Step-by-Step is not for everyone
In all settings, the SbS trials encountered very high drop-out rates. Drop-outs commonly occurred at the beginning of the intervention, but participants also continued to drop-out at later stages of the intervention. The process evaluation took a more detailed look at this (see section 3), but an initial conclusion is that the STRENGTHS version of SbS did not appeal to all Syrian participants but only to approximately 40 to 60%, depending on the country. A noteworthy difference between the three trials was that not only recruitment was much faster in Egypt, but study adherence was also higher as well. Given Egypt's scarcity of evidence-based and accessible psychological services for refugees as well as the higher unemployment rates among participants from Egypt, SbS may have been perceived as without alternative, while participants in Sweden and Germany were aware of other treatment options that may have shaped their expectations of the program (see process evaluation results in section 3 of this report).

Those who complete SbS, profit from it
Conclusions drawn from the Sweden and Germany datasets are limited due to low statistical power. However, the data from Egypt provided indication that the contact-on-demand version of SbS that was developed for STRENGTHS has the potential to provide users of the app with techniques that help with psychological distress and that improve functioning. The exploratory analyses revealed that there were subsamples of intervention completers in all three countries who showed stronger intervention effects. While interpreted with reservations, these findings indicate that SbS in its intended dose can be an effective intervention.

Based on these findings, future work on SbS and similar digital offers for Syrians and other refugee populations should focus on how to build trust towards the approach and on how to increase intervention adherence to ensure that more participants can profit from the intervention. Complementary process evaluation conducted as part of STRENGTHS provided further insights in these areas.

3. Process evaluation

3.1. Introduction

Intervention research focusing exclusively on the question of efficacy usually does not provide insights into whether an intervention is implementable, transferable, cost-effective, and scalable in real-life settings (Skivington et al., 2021). Process evaluation (PE) is one approach to address this issue. PE is viewed as an extensive process that assesses numerous aspects of research trials, such as target group receipt, setting, implementation, and outcome implications, utilizing both quantitative (e.g., questionnaires) and qualitative (e.g., stakeholder interviews) tools (Oakley et al., 2006). As a result, PE sheds light on the "black box" of trials and helps researchers move beyond evaluating the efficacy of an intervention to answer other relevant questions, such as how an intervention could be further optimized and how the results of intervention studies can be transferred into real-world use. Due to its versatility and numerous benefits, PE is increasingly applied in trials (French et al., 2020). Furthermore, experts consider PE a vital aspect of RCTs, particularly within interventions for populations affected by adversity, allowing for deeper insights into such "complex settings" (Massazza et al., 2022). Consequently, the STRENGTHS trials included PE to examine SbS further and widen the research base toward more effective implementation of SbS and similar services in refugee contexts.

3.2. Methods

3.2.1. Objectives

The process evaluation complements the pragmatic RCT results by putting a focus on participant feedback after using SbS as part of the intervention condition. Key objectives are to gather overall user feedback on the relevance of SbS among Syrians, to gather information on potential barriers for accessing and using SbS and to gain in-depth information on how to improve specific features of the app and the SbS intervention approach, including the guidance model chosen for SbS in the STRENGTHS trials.

Further process evaluation was conducted in collaboration with STRENGTHS WP2. This part of the process evaluation focussed on project staff and expert/stakeholder feedback regarding the implementation and scaling-up of SbS.

3.2.2. Data collection

The Process Evaluation Interviews (PEIs) with study participants
Qualitative process evaluation interviews were conducted, using a structured interview guide with probing questions. Interviews were approximately one hour long and were conducted with intervention group participants in all three countries. The interview guide consisted of four parts:

Part I – Introduction: The introduction section of the Interview covered basic information on the interviewee, including reasons for using SbS and experiences with other services for mental health.

Part II – Deepening and broadening: The second part of the interview included detailed questions and probing questions on what participants liked and disliked about SbS. This section also asked about suggestions for improving SbS, the need of an approach like SbS among Syrians and potential barriers to using SbS.

Part III – Usability: Next, a series of questions regarding common usability (i.e., the quality of the app from a users' perspective) dimensions were asked. These questions were based on the established Mobile App Rating Scale User Version (Stoyanov et al., 2016), short uMARS. Instead of assessing these questions in a questionnaire format, they were asked in the interview format to provide the opportunity for probing questions and clarifications.

Part IV – Global feedback: The final section of the interview was based on the last section of the uMARS questionnaire and covered more general questions including an overall star rating (1-5 stars) for the app, question on whether participants plan to continue using SbS, would recommend SbS or would pay for the app. The last question asked participants to name up to three magic wishes aimed at improving SbS.

Semi-structured interviews with staff and stakeholders
STRENGTHS WP2 provided an interview guide for SbS staff, including SbS implementing partners and for key informants (MHPSS providers and policy makers). The interview guide consisted of the following parts:

Part I – Introduction: The introduction section of the Interview covered basic information on the interviewee, including their role and position in the context of SbS provision or health care provision.

Part II – Deepening and broadening: This section of the interview focused on specific observations and lessons learned during the trials as well as on view on intervention characteristics, the e-helper model, and challenges to implementation.

Part III – Scaling-up: In this part of the interview, participants were asked about the scaling-up potential of SbS, potential barriers and facilitators to scaling-up and who important stakeholders for scaling-up could be.

Part IV – Socio-cultural, political, and economic environment: In the final part of the interview, participants were asked about external factors that may shape the implementation of SbS in the respective country settings.

The Client Satisfaction Questionnaire Adapted to Internet-Based Interventions (CSQ-I)
In addition to the qualitative interview, study participants completed the Client Satisfaction Questionnaire (Larsen et al., 1979), an easily scored and administered eight items measure that is designed to measure client satisfaction with mental health services. The CSQ-I used in this study is an adapted version for the evaluation of client satisfaction in internet-based interventions. It was assessed at the post assessment (T2). The 8-item instrument was shown to have good psychometric properties (Boß et al., 2016) and is easy to administer with item scores of 1-4 on a Likert scale. The instrument was included to provide an additional data source for the—otherwise mainly qualitative—process evaluation in STRENGTHS WP6.

3.2.3. Recruitment

Study participants
A maximum variation sampling approach was utilized to recruit a heterogenous sample of participants in the intervention group. Participants were grouped based on key characteristics to ensure equal participation of:
o   Intervention completers and non-completers,
o   women and men and
o   age groups (18-30; 31-49; 50+).

Based on these characteristics, eligible participants were identified. In Germany and Sweden participants received an email invitation. In Egypt participants were contacted and invited by the collaborating NGO. Upon receiving post-intervention invites, a total of n = 40 participants in Egypt, n = 25 in Germany, and n = 10 in

Sweden consented to the interview. All n = 75 interviewees received an information sheet about the study and the interview and provided their written informed consent before the interview.

Staff and stakeholders
For SbS staff and implementation partners, a convenience sampling approach was chosen to gather data from involved personnel in all three countries. A total of 6 staff members in Germany, 2 collaboration partners in Sweden and 1 collaboration partner in Egypt were interviewed. Additional key informants from the (mental) health, refugee, governmental and non-governmental communities were identified through convenience sampling and snowball sampling. A total of 9 stakeholders in Germany, 8 in Sweden and 5 in Egypt were interviewed in a collaborative effort of WP2 and WP6.

3.2.4.   Procedures

Study participants
Syrian native Arabic speakers received interviewer training and conducted the interviews in Germany and Sweden via phone. In Egypt, interviews were conducted by equally trained Egyptian native Arabic speakers on-site. All interviews were audio-recorded and fully transcribed into Arabic. The interview transcripts were then translated into English.

Staff and stakeholders
The interviews were conducted in English or in German. All interviews were audio recorded and then transcribed and—if needed—translated to English. All interviews were conducted online.

3.2.5.   Data analysis

The data analysis for staff and stakeholder interviews was conducted by STRENGTHS WP2 and is described in the reports, deliverables, and the corresponding publications. The following sections will therefore focus on the WP6 work on the participant data analysis.

The qualitative analyses of the PEI transcripts in WP6 were conducted using MAXQDA Plus 2022. The coding scheme was generated through a combination of deductive and inductive methods (Braun and Clarke, 2006).

Usability
For the deductive generation of codes, a combination of an extended version of the Health IT Usability Evaluation Model (Househ et al., 2015) and the usability dimensions of the uMARS questionnaire (Stoyanov et al., 2016) were combined to generate a comprehensive selection of user-centred dimensions for rating the app's quality. The Health-ITUEM is a detailed usability assessment model based on the Technology Acceptance Model and ISO 9241-11 (Brown et al., 2013). The same model was already applied at the formative research stages for SbS in which similar qualitative interviews were conducted to inform the contextual adaptation of SbS (Burchert et al., 2019).

Impact and user experience
The resulting coding system was then inductively extended. To this end, two independent researchers read all interviews and identified potential new codes. These codes were then discussed within the research group and all codes that reached consensus within the team were added to the coding system. Most inductively identified themes were based on accounts of how participants viewed specific aspects or features of the SbS app and were clustered under the dimension of either impact (i.e., specific outcomes that participants attributed to using the app) or user experience (UX). Whereas usability themes depict the functional aspects of using an app, UX themes address the more subjective component of user feedback.

Coding system
The final coding system is depicted in Table 14 and contains the three main nodes of impact, usability, and user experience. For each of these main nodes several sub-nodes were identified and coded that cover facets of the overarching theme, e.g., the impact that using SbS had on participants was commonly described as either impacts on a person's (mental) health, impacts on a person's information needs or as impacts on a person's behaviour.

In addition to the theme, each coded section of the transcripts was also marked as either a positive comment (+) or as a negative comment (-), as suggested by (Brown et al., 2013). Since interviewees were encouraged to also provide suggestions for improvement, an additional code for suggestions (S) was added. The interview transcripts were coded by three independent researchers. Two coders worked with the Arabic transcripts and the third worked with the English translation. Afterwards, the codes of all three coders were compared and any ambiguities or deviating results were discussed and resolved to create the final dataset.

Additional codes
In addition to the codes outlined in Table 5, the coders also collected all mentions of potential barriers to accessing SbS, potential barriers when using SbS, suggestions for improving SbS and the answers to the global feedback questions (e.g., a star rating for the app).

Table 5. Coding system for process evaluation interview transcripts

Themes	Definitions	Examples (coding)[3]
Impact		
Health impact[1]	Impact on users' (mental) health involving measurable health markers	G: "[It] helped me a lot to reduce stress and nervousness during my study." (+)
Information needs[1]	The extent to which information content impacts users' knowledge	S: "I felt the information was a bit superficial or too general in some parts." (-)
Behaviour[2]	Other system-specific outcomes impacting users' behaviours	E: ". . . it taught me how to get close to people and make friendships with them . . ." (+)
Usability		
Learnability and ease of use[1]	The initial effort of learning how to operate and navigate the app	E: "It took me some time to learn it . . ." (-)
Performance speed[1]	Efficiency and responsiveness of the app's features and interfaces	S: "It was fast and did not hang." (+)
Flexibility and customizability[1]	Providing alternative ways for accomplishing tasks allowing users to operate the system as preferred	G: ". . . when I didn't want to listen to the spoken text, I simply turned [it] off." (+)
Technical reliability[2]	The capacity of the app to function without failure	S: ". . . I couldn't save the things I was writing . . ." (-)
User experience (UX)		
Aesthetics[1]	Perceived visual design qualities of the app	E: ". . . if you removed the colours orange and green, it would look better." (S)
Motivation and engagement[1]	Perceived factors that affect motivation and interest in using the app	G: "There can also be motivational and encouraging notifications or messages that provide psychological support to a person." (S)
Anonymity[2]	Perceived factors related to privacy when using the app	G: ". . . [as] it is a secret app on your phone, it's much easier. This feature reduces the fear because the identity remains secret." (+)
Perceived flexibility of use[2]	Perceived time and place flexibility of use with consideration of special needs	S: "Whenever you want, while sitting at home alone, you can open the app and use it without any pressure or scheduling commitment." (+)
Guidance model[2]	Perceptions of various aspects of the guidance model, including e-helper characteristics	G: "In general, it would be better if the [e-helpers] were specialists and graduates." (S)

Themes	Definitions	Examples (coding)[3]
Intervention content[2]	Comments on intervention-specific features	E: "The stories were depressing." (-)
Perceived credibility and trust[2]	Perceived trust in the app as a reliable source of information/support	E: "It's not always the case on the internet, but your app seems to be professionally developed by specialists." (+)
Contextual adaptation[2]	Perceived quality of the cultural and contextual adaptation of the app's content	G: "[The protagonists] were diverse and included different categories of our Syrian society." (+)

Note. [1]Themes based on the Health-ITUEM and uMARS; [2]Additional themes generated inductively. [3]Responses were coded as either positive (+), negative (-) or suggestion (s); E = comment from Egypt, G = comment from Germany, S = comment from Sweden.

3.3. Results

3.3.1. General feedback

Need for SbS among Syrians
Most participants said that they see a need for SbS among Syrians in their country of residence.

Recommending SbS to others
Another perspective on the perceived value of SbS was given after being asked whether participants would recommend the app to others. Again, the large majority said "yes", while some participants said "no", and few participants said they would only recommend it if they were sure the person would accept the idea. Overall, many participants mentioned in their answer to this question, that they already recommended SbS to family members or friends.

Paying for the app
When asked whether they would be willing to pay for SbS if it would be released in the stores as a commercial app, few participants said "yes" but more participants indicated that they would not be willing to pay for SbS. The remaining said they would "maybe" pay for the app but only if certain conditions were met. These conditions included that their financial situation would allow it, that they would continue to see positive effects or that the app would receive further updates in the future with relevant content for participants. Some participants also indicated that having the opportunity to talk to a mental health professional would be added value that would let them consider paying for SbS.

Future use
After completing the study phase, SbS was kept available to participants to use as they wished. Consequently, participants were asked whether they intend to keep using the app in the future. To this question, many participants answered yes, while some indicated that they "maybe" will use SbS again and few answered that they won't be using SbS anymore.

3.3.2. Access and usage barriers

When asked about access barriers that may prevent potential users of SbS from starting the program, many participants mentioned stigma (self or external). This barrier was often pointed out in combination with mental health literacy as another key barrier.

The initial impression of trustworthiness and privacy when learning about the SbS app was another commonly mentioned barrier. Participants indicated that Syrians may mistrust the offer due to fear of privacy breaches

such as username leaks. A related barrier was the fear of legal repercussions when sharing information about one's mental health.

Finally, daily responsibilities were another common barrier as participants indicated that many Syrians had other, more pressing matters to attend to and wouldn't have the time to use SbS.

For those who already started using SbS, several usage barriers were identified that may have caused low intervention adherence and study drop-outs. The most common barrier were the extensive questionnaires that had to be completed prior to starting with the first session of SbS. While not technically part of the intervention, participants' overall user experience with SbS was significantly affected by the large number and perceived repetitiveness of the assessments.

The previous quote illustrates that some participants also considered daily responsibilities as a potential barrier after starting SbS. A smaller number of participants also reported that realizing that SbS was not having the expected effect was a reason to stop using it.

3.3.3.   Impact, usability, and user experience

Impact
Health impact
The most common impact of using SbS reported by participants was a reduction in stress symptoms after using SbS, followed by improvements in wellbeing/functioning and mood.

Information needs
General improvements in mental health literacy were reported by some participants. A common topic related to this was that the use of SbS lead to more self-reflection in participants and enabled them to look at their personal situation and their options from a different perspective. Several suggestions for improvement were given, mainly focusing on delivering more psychoeducational information and addressing other mental health concerns.

Behaviour changes
Several respondents reported that SbS positively influenced their behaviour in various ways, with some becoming more physically active, meeting with friends more often, some reported being able to better handle challenging situations with others and again others reported healthy behaviour changes such as doing more sports or stopping to smoke. Finally, respondents indicated that features of SbS enabled them to recognize warning signs early and that SbS taught them techniques to counteract symptoms without having to use actively use the app anymore.

Usability
Learnability and ease-of-use
Many respondents spoke positively about this dimension, explicitly noting that the app was generally straightforward and easy to use and that navigating through the app user interfaces was simple. Issues were reported rarely but sometimes occurred in relation to finding the build-in messaging system for contacting the e-helpers. Some participants expressed concerns about older people being initially overwhelmed when using the app and recommended that the icons and symbols could be more intuitive and enlarged for that user group.

Performance speed
The app's performance was often seen as very good.

Flexibility/customizability
Participants often described the app as flexible and adaptable to the user while not mentioning specific aspects. Those who gave specific examples frequently spoke positively about having different options for user input, such as text, audio, and picture input and the possibility to listen to audios instead of reading. Another commonly mentioned positive aspect was the time flexibility of use.

Technical reliability
This dimension refers to the app's capacity to function without errors and was generally commented on in a positive manner. Minor issues identified were missing notifications for a small number of participants as well as rare issues with data synchronisation for users with bad internet connectivity.

User experience
Aesthetics
Most respondents commented positively on the app's overall look. Other positive remarks were related to user interface, illustrations, colours, and narrator voices in the audio recordings. Negative comments focused on the illustrations being too childish or cartoonlike. Consequently, the most cited suggestion about the aesthetics was to bring the illustrations closer to reality.

Motivation/engagement
Most interviewees found SbS interesting and entertaining or fun owing to elements such as the narratives or the engaging practical exercises. However, the numerous and partly long questionnaires, as well as the repetitive content (e.g., summary at the end of a session and recap at the beginning of a new session) negatively impacted the motivation and engagement of some users. Participants suggested several improvements to boost user engagement including 1) motivational messages, 2) more relatable narratives and exercises, 3) entertaining elements such as quizzes, and 4) rewards for completed exercises (e.g., with stars). Another user experience element related to engagement was the feeling of communicating with a real person when using the app. Several participants indicated this while explicitly not referring to the e-helper but to the narrative self-help elements of the app.

Anonymity
The option to receive support without seeing a professional face-to-face was commented on by several participants with exclusively positive statements. The comments stated that the app's anonymity made users feel less embarrassed, afraid, or generally more comfortable as their identity was protected.

Perceived flexibility of use
Many participants considered this dimension one of SbS's strongest aspects and frequently named the ability to use the app regardless of time and location and the option of audio support as core advantages of the approach.

Guidance model
Views on various aspects of the contact-on-demand support model were raised in the PEIs. Some expressed their satisfaction with the e-helper contact. Positive comments regarding the e-helpers characteristics mainly focused on them being Syrians and having the required cultural understanding of the users and their living conditions.

Additional feedback from the PEIs indicated that a substantial number of participants wished for actual contact with a mental health professional (i.e., a doctor, psychiatrist, or psychotherapist), instead of working with pre-defined content.

Intervention content
This theme is a cluster of different aspects and features of the app. On the one hand, the text length and correctness, the weekly rhythm for unlocking new sessions, and the audio quality were all regarded as positive

characteristics of SbS. On the other hand, some found the content of SbS insufficient or partially repetitive. One element that was seen as especially repetitive were the questionnaires. The replies coded for this theme indicate that participants did not differentiate between SbS session content (i.e., narratives and exercises) and the study assessments (i.e., baseline, post, and follow-up questionnaires). Consequently, a common suggestion was to shorten the questionnaires. In addition, participants suggested adding additional content, such as more narrator versions, new sessions, or new exercises.

When asked about specific features, the most positively regarded exercise type were the audio exercises, such as the Slow Breathing exercise. Other positive aspects were the protagonist narratives, the exercises in general, and the features Mood Tracker and Activity List. In a few interviews, the exercises Kind Words, Gratitude List, and Social Activities received negative comments, either because their purpose could not be grasped or because their implementation was not feasible.

Perceived credibility/trust
Most interviewees described SbS as a trustworthy and credible source of support. This was often attributed to the program being provided by a university or—in the case of Egypt—due to being approached by a trusted organization. For a few others, the data security measures provided in the SbS privacy policy were a contributing factor for trust.

Contextual adaptation
Generally, many participants described SbS as appropriate for the target group. The Levantine dialect received the most positive feedback and was perceived as closer to Syrians, more straightforward, and more convenient. Nevertheless, few preferred standard Arabic. Moreover, culturally appropriate illustrations and characteristics of the protagonists (e.g., with or without a headscarf or beard) were praised.

While intervention content was relevant to many, but some could not relate to the protagonist's story and answer options in the questionnaires. Therefore, it was often recommended to include more relevant protagonist narrative versions and to tailor content to users' individual experiences and symptoms.

3.4. Discussion

3.4.1.   Main Findings

Perception of SbS
The general tone of feedback received through the process evaluation interviews on SbS implementation in Germany, Sweden and Egypt was overwhelmingly positive. Throughout the interviews, participants expressed a large need for offers like SbS in the Syrian communities, an overall positive impression of the quality of the SbS content and the technical implementation of the app as well as appreciation for the cultural adaptation and accessibility features. Positive effects of SbS on mental health or behavioural outcomes were reported commonly and the program was also seen as a source of credible information on mental health topics. In addition, participants often expressed trust towards the program and its security when it comes to protecting their privacy.

In the stakeholder interviews, overall e-health acceptance was found to be high in all three countries and—while at varying stages of implementation—it was evident that digital mental health solutions were seen as having a clear raison d'etre in all three countries. The COVID-19 pandemic was partly facilitator, partly barrier to the implementation of SbS in the STRENGTHS trials. While posing major challenges to outreach, the pandemic may have substantially accelerated the digital transformation in health care systems.

Conclusion:
Based on these findings it can be concluded that the SbS implementation in STRENGTHS is a promising approach to providing low-threshold support in a population that is open to digital interventions.

Adherence and user engagement
Despite the positive reception of SbS in the PEIs, the SbS trials in Germany, Sweden and Egypt had high drop-out rates. While this is not uncommon in low-threshold, self-guided, digital interventions, the high drop-out rates indicate that SbS was not relevant or engaging enough for a substantial part of the study samples, especially in Sweden and Germany. Participants in the interviews provided several potential reasons for this, including common barriers such as stigma or mental health literacy that may play a role in non-start attrition.

Further, specific aspects of SbS, including the lengthy and repetitive assessments, a lack of personal guidance by mental health professionals due to the self-help approach or a lack of time due to daily responsibilities were common themes that may explain dropouts after starting the program. In a more detailed analysis of the specific comments and suggestions provided in the interviews, it became apparent that participants may have expected more personal contact with experts through the app, leading them to dropping the app after realizing that it focusses on self-help. In addition, not all participants may have found the narratives provided in SbS relevant for their current living situation. While SbS provided very detailed descriptions of protagonists and how they used the SbS techniques in their daily life, the spectrum of concrete issues (e.g., marriage problems, child rearing problems, financial problems) that could be included in these stories was limited. Consequently, several respondents suggested that different narrative versions suiting better the current life circumstances and challenges of Syrians—especially in Germany and Sweden—should be created. Since the outbreak of war and their flight, most Syrian refugees have now lived for several years in host countries and are likely to experience other stressors and burdens (e.g., homesickness or racism) than those primarily covered by the narrative content in SbS (e.g., losing or taking care of a displaced family member). This feedback points out a general issue with narrative formats in e-mental health as new content versions require substantial time and monetary investments for story creation, illustrations, and audio recordings.

Providing SbS as part of a scientific study had a few additional implications for user engagement. A key finding was that participants often didn't differentiate between study content (i.e., questionnaires) and SbS content (e.g., narratives or exercises). The questionnaires were perceived as a part of SbS and participants overall experience with the app was significantly affected by their feelings towards the questionnaires. Some found the questions very helpful and even went so far as to suggest making the narratives optional so users can choose to only do the questionnaires. On the other hand, the relevance and scientific purpose of the questionnaires was not always clear, and users criticized limited answer options and repetitiveness as negative elements of the SbS intervention.

Conclusion:
In summary, the SbS version used in STRENGTHS requires further improvements in the areas of content relevance and tailoring the content to individual user needs. The perception of SbS may also have been affected by study-specific components such as the assessments which may require adjustments to study design for future research on SbS.

Guidance model
One of the most common suggestions among participants was to include direct personal contact (via phone or in person) with a mental health care professional. While Syrian e-helpers were considered a positive aspect of the offer—especially given their shared cultural background—the contact-on-demand feature was rarely used and mostly had the character of technical support. The second most common topic in contact-on-demand were question on referral to organizations or mental health professionals. Stakeholders, in the other hand, were open to non-professionals as a source of support in mental health settings. This discrepancy is an important finding as it underlines a mismatch between structure that are created locally and expectations in the target population. Especially in countries like Germany and Sweden that provide face-to-face

psychotherapy as part of their health care systems, Syrians expect to receive the same treatments that the local population has access to. Digital offers such as SbS can therefore be perceived as an inferior alternative, instead of as a useful addition to existing offers.

Conclusion:
The findings are a clear indicator that the chosen guidance model was not a good match with participants expectations and the process evaluation has clearly shown that participants expected a more personal form of guidance. The findings indicate that there needs to be a form of promotion of these approaches that considers the Syrian cultural background and expectations when searching for mental health support. Stakeholders provided several pathways to build trust, including recommendation by general practitioners, building trust through social media influencers or individual champions in the community or public awareness campaigns.

Design and Learnability and technical reliability
Starting with the formative research phase and throughout the iterative software development process, user-centred design principles were at the core of the contextual adaptation of SbS for the STRENGTHS trials. The process evaluation provided strong evidence that the design and user interfaces created for the app were appropriate, easy-to-learn and intuitive—even for those with limited tech literacy. Reports on technical issues were very rare in the PEIs and didn't occur often in support messages and emails sent to the e-helper team. Internet connectivity issues were among the more common issues but were largely absorbed by the offline capabilities of the software that made SbS very robust towards unstable internet connectivity. Participants praised the configuration options of the program, including the optional audio support and didn't report issues with the app's performance speed. This is a very positive finding due to the large variety of smartphones that study participants may use to access SbS. This variety commonly introduces technical complexity due to outdated software versions, old hardware, or limited storage space on the devices. Issues with app performance are often caused by this complexity and the absence of these issues in the interviews underline that the chosen software framework and the overall quality of the code resulted in a very robust solution.

These findings are complemented by the platform logs of the software created for STRENGTHS. Staff reports as well as the logs show that the project was successful in hosting and maintaining the three parallel trials with a total of 2051 accounts created with no downtime and no security incidents (i.e., hacks) as well as no lost or compromised data throughout the whole project period. Given the sensitive nature of the data on the SbS platform and the strict regulatory environment in the European Union, these findings are essential in building trust and as a proof-of-concept that e-health solutions can be securely and reliably provided to global target populations. Stakeholder interviews added additional perspectives to these aspects by stressing the importance of regulatory frameworks and trust in the digital systems.

Conclusion:
The user interfaces and the design created for SbS were effective in enabling all participants to use SbS without encountering usability issues. Furthermore, the software platform has proven to be reliable, secure, and robust towards common barriers to e-mental health implementation, including outdated devices and limited access to the internet. At the same time, the project as shown that the creation of secure and robust software is time-consuming and requires constant effort to keep the system up to date. This adds a unique cost factor that needs to be considered for scaling-up.

3.4.2.   Strengths and limitations

The process evaluation provided a comprehensive set of themes covering major usability and user experience dimensions that are also found in established frameworks. Furthermore, the N = 75 participant interviews provided a large enough sample to reach saturation (i.e., there were no new themes identified in later interviews). The large sample size not only allowed the identification of rare topics and new ideas to improving

SbS, but also the identification of topics that were of particular importance to a larger number of participants. However, due to the high drop-out rates and a low response rate to interview invitations in Germany and Sweden, the sample cannot be seen as representative for the whole study population. Participants who agreed to be interviewed may have had a more positive view on SbS, which could have introduced a bias in the analyses.

While subjective in nature, the qualitative analyses were conducted using a pre-defined coding system and were conducted by three independent raters. This ensured that the results were consolidated and less affected by individual researcher bias that may occur in qualitative research.

Finally, a major limitation of the research conducted in STRENGTHS WP6 is that the trials and the process evaluation were conducted during different stages of the COVID-19 pandemic. Not only did the pandemic have an impact on participants (mental) health but it also affected the relevance of certain components of SbS (e.g., content on social activities). An overall reduction on available face-to-face offers during the pandemic may also have led to more participants looking for contact to experts in a digital format, which turned out to be the most requested feature for future versions of SbS.

3.4.3.   Recommendations for further scaling up

Adjustments to the SbS intervention
The findings in the process evaluation of the trials on SbS in STRENGTHS lead towards two potential pathways for future scaling-up of the SbS intervention itself. These recommendations are based on the most common participant feedback.

Path A – Adding low-intensity guidance
To match participant expectations and to improve adherence, adding guidance in the form of mandatory and regular messenger or phone contact—instead of optional contact—could result in an overall higher number of participants who can profit from using the app. This approach was taken by other implementations of SbS outside of STRENGHTS. For example, in Lebanon the Ministry of Health and the WHO implemented a version with regular guided support through 20-minute, weekly phone calls. In a study in this version of SbS, adherence rates and intervention efficacy were found to be improved (Cuijpers et al., 2022). Therefore, guided support could increase the overall uptake of SbS in the context of STRENGTHS. However, while this approach may increase the number of participants who may profit from the program, it also significantly increases the cost of providing SbS due to personnel costs, facility costs, training costs and the general logistics involved in maintaining a reliable and responsive team of e-helpers over extended periods of time. The scalability of this approach is therefore somewhat limited.

Path B – Tailoring SbS content to user needs
A second option for scaling-up is to maintain the already highly scalable self-help approach but to address the user feedback identified in the PE by improving SbS content and introducing tailoring to the program.

An element of choice—e.g., allowing users of the app to pick topics that are relevant to them—is missing in the current "one-size-fits-all"-version of SbS. By providing smaller chunks of topic-specific content, other common issues around content relevance can also be addressed. E.g., participants in Germany and Egypt often criticized that the narratives didn't address issues around discrimination, bureaucracy in the host country, the language-barrier and integration. The research in STRENGTHS has shown that common topics shift over time and that the e-mental health approach is less flexible in reacting to these shifts in comparison with face-to-face versions of PM+. However, a more flexible system of content chunks that user can pick from and that can also be updated and expanded over time, could provide a setup that turns this disadvantage into an advantage of the digital approach. The narrative approach was found to be a rather controversial topic, liked by some participants but disliked by others. A common suggestion was to make the narratives optional, which would

become a possibility in a tailored version of SbS. Instead of picking one protagonist at the start of the program, participants could find a selection of narrators in different sections of the available content and pick which one's they would like to learn more about.

Combined with a smaller selection of assessments that could result in immediate recommendations on what content to start with, the app could be perceived as a personal guide by more participants and the inclusion of questionnaire could be perceived as less of a disruptive factor in the overall user experience.

Integration scenarios for Germany, Sweden, and Egypt
The stakeholder interviews conducted in collaboration with WP2 resulted in country-specific integration scenarios that were developed based on participants input on influential actors in their respective countries health care systems. In Egypt, a promising integration scenario involves a focus on funding by international non-governmental organisations in combination with a close collaboration with the local ministry of health. In this scenario, the main provider of SbS would be the NGOs with the aim of long-term integration and structure building. In Sweden, digital health is already a key component of public health care and is commonly offered in primary care facilities. However, offers are commonly developed for the local population and the maintenance of culturally adapted offers requires additional public funding, which would be the ideal scenario in a Sweden-wide scaling-up of SbS. In Germany, there is still a lack of publicly funded digital health solutions. While this is slowly changing, a civil society approach to implementing SbS is still considered to be more feasible. Germany has established networks of organisations for refugee care that can function as facilitators for making SbS widely available. Financing in this scenario would still require external funding through donors, governmental grants, or health insurance (to a lesser degree and with additional prerequisites).

3.4.4.   Outlook

The STRENGTHS trials on SbS were successful in establishing that a low-threshold digital solution like SbS can be made available to a large number of users who reside in different geographical regions while still maintaining a centralized technology and support infrastructure. These unique characteristics of the e-mental health provision model tested in STRENGTHS make the offer highly scalable. With further improvements to the software and intervention structure as outlined above and additional investments in building local structures according to the integration scenarios, e-mental health solutions can be scaled-up population wide.

Two pathways for the future development of improved versions SbS were identified as the main result of the process evaluation. These pathways are both considered viable and not mutually exclusive. Path A—i.e., to put a stronger focus on guidance—is more viable for implementation in existing structures. This approach is promising in settings with a smaller number of clients and sufficient funding opportunities for staff e.g., in Germany and Sweden. Path B—i.e., to improve automatic tailoring to user needs within the app—is more viable in resource-limited settings with a larger target population e.g., in Egypt. Path B would also appear to be the preferred option for future scaling-up in Syria itself due to local resource limitations, barriers to accessing the country and the large target population.

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