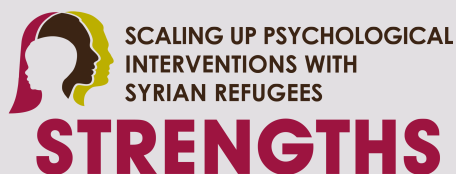




Economic evaluation of Implementation: PM+, SbS and EASE

DELIVERABLE 7.2



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1. Executive summary

Worldwide by mid-2022 there were more than 103 million forcibly displaced people. This includes 6.8 million refugees from Syria, more than any other country. Protecting and strengthening the mental health of refugees fleeing conflict is a pressing global mental health issue, further exacerbated by 5.8 million Ukrainians now seeking refuge. Refugees and internally displaced people are at heightened risk of developing many common mental health conditions including depression, anxiety and post-traumatic stress disorder. Poor mental health, if untreated in refugees, can have long term mental and physical health consequences that may persist even many years, as for instance seen in conflict-affected people in the former Yugoslavia many years after that conflict ended. Early intervention to meet their needs may help to avoid some of these initial and longer-term impacts, but evidence on cost effectiveness is limited. Having a better understanding of the strength of the economic case for action is important when making the case to national governments, as well as international donors and relief agencies/non-governmental organisations for more investment in measures to support the psychosocial health of refugees and other displaced people.

This deliverable sets out the methods used within the STRENGTHS project to assess the cost-effectiveness of the WHO scalable psychological interventions PM+, gPM+ and SbS among Syrian refugees. In addition, we also describe methods used for a costing analysis of the EASE intervention in Lebanon. We also include results of economic analysis from pilot PM+ studies in the Netherlands, Switzerland and Türkiye, as well as analyses from the main PM+ studies in Jordan, Netherlands, Switzerland and Türkiye and SbS studies in Egypt, Germany and Sweden. We observe that the economic case for intervention comparing the costs and consequences of intervention with impacts on quality of life (the primary outcome in health economic studies) varies considerably across settings. However, if costs of implementation can be reduced, for instance through lower training costs, and any quality of life gains are sustained beyond 3 month follow up, then the economic case for investment is strengthened considerably in many settings. There may also be longer term impacts on health and social care utilisation that are not visible at 3-month follow up. A more extensive version of the report will be available from the authors once the results of the individual studies have been accepted for publication.

2. Background

Protecting and strengthening the mental health of refugees fleeing conflict is a pressing global mental health issue (Patanè et al., 2022). Refugees and internally displaced people are at heightened risk of developing many common mental health conditions including depression, anxiety and post-traumatic stress disorder. By mid 2022, 103 million people had been forcibly displaced from their homes (United Nations High Commission for Refugees, 2022b), more than doubling the number a decade earlier (United Nations High Commission for Refugees, 2022a), including 40% who have fled to other countries. 74% of refugees are hosted in low and middle-income countries (LMIC)s.

The Syrian conflict has been major cause of population displacement, with some neighbouring countries having become safe havens for millions of conflict-affected refugees. Almost 7 million refugees have sought refuge, primarily in neighbouring countries, as well as in Europe. For example, Türkiye, the country that hosts the highest number of refugees worldwide (3.7 million refugees), had given “under temporary protection” status to 3.5 million Syrians, nearly all of whom live in the community, while Jordan now hosts more than 676,000 Syrian refugees, of which more than 133,000 live in refugee camps (United Nations High Commission for Refugees, 2022c). This can present great logistical and financial challenges for host countries; in Lebanon, relative to the national population, refugees and displaced people make up 1 in 6 of the population (United Nations High Commission for Refugees, 2022b). These challenges internationally have been exacerbated further in 2022 by the conflict in Ukraine; by mid-2022 5.4 million Ukrainians had to seek refuge in other countries, mainly in Europe (United Nations High Commission for Refugees, 2022b).

Poor mental health, if untreated in refugees, can have long term mental and physical health consequences that may persist even many years. This can be seen in conflict-affected people in the former Yugoslavia many years after that conflict ended (Priebe et al., 2009, Sabes-Figuera et al., 2012). Exposure to severe stressors, such as violence, detention, and lack of basic needs have been widely reported. After migration, refugees may continue to experience hardships such as lengthy asylum procedures, financial insecurity, and social isolation (Hajak et al., 2021, Juárez et al., 2019). All of these factors can be risk factors to mental health and wellbeing. Meta-analytic evidence shows rates of common mental disorders (CMDs) as high as 32% for depression and 31% for posttraumatic stress disorder (PTSD) among refugees and asylum seekers (Blackmore et al., 2020, Hoell et al., 2021). Prevalence rates among Syrian refugees in Türkiye were 34.7% and 19.6%, respectively. (Acarturk et al., 2021) Although mental health services are available in high-income countries (HICs) there may be legal and regulatory barriers to access (Satinsky et al., 2019), as well as

practical problems such as the need for translators, cultural sensitivity and stigma around mental health (Grochtdreis et al., 2021, Gil-Salmerón et al., 2021, Bhui, 2022, Björkenstam et al., 2022).

Early intervention to address mental health conditions, if effective, may help to avoid some of these long term health and wider impacts, including avoidable economic costs. A key challenge, therefore, particularly in low and middle income countries but also in high-income countries, is obtaining timely access to mental health care. This lack of access is problematic. In Switzerland for example, the availability of psychological care in specialised facilities can be scarce and costs for interpreters are often not covered (Müller et al., 2018), while in Germany, for example, refugees have faced regulatory barriers making it more difficult for them to access many health care services (Bauhoff and Göppfarth, 2018, Bozorgmehr and Razum, 2015). In countries such as Lebanon and Jordan specialist mental health care services are very limited, moreover, out of pocket payments (Doocy et al., 2016) and other regulatory hurdles may limit access to many health care services for refugees. Even if these barriers are removed there may still be a reluctance to come into contact with specialist mental health services because of the stigma that can be associated with poor mental health (Bawadi et al., 2022).

This treatment gap in mental healthcare is especially problematic, considering that untreated mental health problems tend to become chronic. For example, long term analysis in Switzerland using health insurance system data indicates asylum seekers with mental health conditions have increasing health care costs over time compared to asylum seekers without these conditions. A lack of early intervention to identify and refer asylum seekers to appropriate services may contribute to this increasing cost trajectory (Tzogiou et al., 2022). Poor mental health is also likely to hinder integration and participation, which, given the predominantly young age of those affected, leads to a loss of productive years of life and highly individual, family, and societal long-term costs (Schick et al., 2016).

One way to overcome some of these issues is to move away or 'taskshift' away from a reliance on specialist mental health service providers to services that can be provided through primary care and other community health services, including delivery by lay practitioners. This approach has been used to implement the use of brief psychological interventions to address multiple mental health conditions. One such intervention is Problem Management Plus (PM+), a five-session programme developed by the World Health Organization (WHO) to address poor mental health in individuals affected by adversity, such as conflict (Dawson et al., 2015). It is a transdiagnostic intervention, intended to reduce many different common mental disorders, through a common approach and can be delivered in individual or group formats in five weekly sessions. It can be delivered under supervision by peer lay facilitators after 8-days of training. Studies on PM+ in non-refugee samples in Pakistan and Kenya previously have shown its effectiveness in reducing depression, anxiety, PTSD,

functional impairment, and self-identified problems (Bryant et al., 2017, Rahman et al., 2019). Another potential intervention is an online delivered brief programme, Step by Step (SbS), focused on addressing depression (Carswell et al., 2018). Online interventions, if effective, potentially may be easier to scale up than face to face interventions. Brief psychological interventions targeted at adolescents are also being developed. The Early Adolescent Skills for Emotions (EASE) brief intervention is another face to face intervention intended to address depression and anxiety, as well as other internalising disorders. (Dawson et al., 2019)

It is important to generate more evidence on the implementation of such interventions in a range of different contexts and settings. In response to the challenges of refugee mental health the STRENGTHS consortium has been assessing the effectiveness, cost-effectiveness, and implementation of brief psychological interventions for Syrian refugees in countries in Europe and the Middle East, including group and individual versions of PM+, SbS and EASE (Sijbrandij et al., 2017).

This report focuses on the economic analysis in STRENGTHS. Despite the growing numbers of refugees being hosted in low, middle and high-income countries around the world, and their potential economic and societal impacts, very few economic evaluations focused on the case for investing interventions for refugee mental health have been published. (McDaid and Park, In submission). Arguments illustrating that there is an economic, as well as moral and public health, imperative to invest more in global mental health may help facilitate implementation.

3. Aims

Our aim was to assess the strength of the economic case for investment in the implementation of PM+ and SBS in improving the mental health of Syrian refugees in both Europe and in the Middle East. We were interested in examining the short-term impact of intervention on the use of health care services, as well as participation in usual activities such as being in employment (where permitted) or education at 3 months post intervention use and then looking further at longer terms changes at 12 month follow up. We also looked at the economic costs and consequences of investing in EASE for adolescents in Lebanon.

4. Methods

In this section we set out the broad methodology used to conduct the economic analysis across the different STRENGTHS settings. While this broad methodological approach is consistent across all settings, there are some differences in approach across countries/settings which reflect differences in health care system structures, as well as contextual factors such as whether STRENGTHS participants were living in the local community of their host countries, or as was the case in Jordan, in a closed refugee camp.

We begin by first briefly describing the overarching economic analysis methods and then provide information on the design of trials within which the economic analysis is embedded in each of the different country settings, but further detailed information on specific trial methodology is available in other STRENGTHS reports related to work packages 4, 5 and 6.

4.1. Economic evaluation methods

Our primary objective is to assess the cost effectiveness of the PM+ and SbS interventions in each of the country settings compared to enhanced or usual care. This was done in parallel to work to assess the effectiveness of these interventions. In addition, we are also examining the economic case for the EASE intervention in Lebanon, although we cannot undertake the same type of economic analysis there, as the outcome measures collected were different (See Sections 4. 2 to 4. 4 below for more information on each trial).

In most settings our analysis is undertaken from three perspectives. The primary economic analysis is performed primarily from a health system perspective, including costs associated with the delivery of PM+ / SbS, as well as use of other health care services, including any use of traditional healing. While our main focus is that of potential health care funders (such as international donors or national health systems), we are also looking at the economic case from the perspectives of refugees themselves, looking at their out-of-pocket costs and timecosts (PM+ trials only) and society as a whole. For each of these differing perspectives we are assessing the economic case at two time points: after 3 and 12 month follow up periods.

Identifying, measuring and valuing health service and wider resource impacts

Economic evaluation involves the comparison of both the costs and outcomes of two or more interventions. We wanted to see if any improved outcomes linked to the use of PM+ or SbS would be associated with any significant change in the use of health services; better access to brief psychological interventions could, for example, mean less need for emergency inpatient mental health care. It might also increase confidence to access general health services, potentially helping to avoid more serious health problems presenting to health systems at a later stage.

There are different potential approaches to collect health service utilisation data in an economic evaluation. One approach is to make use of data available from electronic health records; however, as refugee access to health care systems is not always through national health systems, as well as a lack of such electronic records in many STRENGTHS countries for refugees, this approach is not feasible. Therefore, we designed bespoke questionnaires tailored to reflect the health systems in each trial setting in order to collect data information on service use. Participants are asked to recall their use of services over the previous three months at baseline and then at 3 and 12 month follow up periods.

This was done using a modified version of the Client Service Receipt Inventory (CSRI) (Knapp and Beecham, 1990). (Versions of this questionnaire in Arabic are available on the STRENGTHS website). Each CSRI was developed iteratively for each trial setting, and then translated into Arabic. While this approach has been used effectively in both high and low income countries, including in work for the assessment of brief psychological interventions (Patel et al., 2017, Weobong et al., 2017), we tested the modified versions of the CSRI as part of pilot studies in the Netherlands (de Graaff et al., 2020), Switzerland (Spaij et al., 2022) and Türkiye (Acarturk et al., 2022). The pilot studies revealed that the instrument was well understood and completed quickly without difficulty.

In all PM+ trials the CSRI collected information on participant self-reported contacts with different community health care workers and traditional healers, as well as outpatient visits and inpatient stays in clinics and hospitals. We distinguished between the use of specialist community and hospital psychiatric services and general health services. Information on the use of medications was also collected. We also collected information on the use of traditional and complementary medicine, for instance use of acupuncture and massage therapy. In the PM+ and EASE trials we further asked about the typical duration of contact, any out-of-pocket fees paid, as well as travel time and costs and waiting times. Secondary economic analysis performed from a refugee perspective compared outcomes with out-of-pocket costs reported by refugees in the CSRI for health service use, as well as placing a monetary value on reported time taken

travelling to, waiting for and receiving health care services. In all countries the CSRI also asked individuals to report days out of work, as well as time out of work by up to two friends/family members who had to provide care and support for them. We also asked individuals in the PM+ trials to estimate loss of income due to time out of work.

For the SbS trials we had to modify the CSRI further so that it was practical enough to be used on mobile devices and online rather than on a face-to-face basis. This led to a shorter set of questions – as the fall-off rate for completion of all the various STRENGTHS questionnaires online may be high. We therefore did not ask about the duration of contacts, nor about travel time or out of pocket fees. Another limitation is that hospital contacts solely covered contacts related to participants mental health and not also their physical health, so we may miss any benefits of reduced use of general health services. We did however collect information on days out of unpaid or paid work for participants.

In addition to using the CSRI for the PM+ and SbS studies involving adults, we have also developed a specific CSRI to capture information on the experiences of children in Lebanon (via their guardians). This child-focused version of the CSRI takes account of impacts on child education as well as work, for example, in addition to impacts on health. Impacts on parents/other family members taking time away from usual activity to support the child were also documented. Out of pocket fees for health care services were also documented.

For each type of health service use in each country setting we also had to undertake a detailed exercise to source appropriate local unit costs for contact with these services, as well as for the cost of medications. Some of these costs were identified from national health system tariffs and drug cost tariffs, some from academic publications and others from expert opinion. For example, in the Netherlands unit costs were attached to health service utilisation using published tariffs used in the Netherlands (Hakkaart-van Roijen et al., 2015) and Medication reimbursement rates were obtained from the Netherlands National Health Care Institute (Zorginstituut Nederland, 2020). Some tables with sources of unit cost data in different countries are shown later in this report. For productivity losses for trial participants and family/friends we made use of loss of daily income values provided by participants but also valued unwaged time using at minimum wage levels in the host country, regardless of individuals legal right to work.

PM+ training, supervision resource and delivery costs were obtained from project records. As we illustrate in the brief descriptions of each country trial, in addition to the direct costs for session helpers/ facilitators, there are initial costs of training for helpers/ facilitators, as well as regular supervision. Other costs can include various travel-related expenses, such as costs for vehicle rental and maintenance, as well as costs for

printing manuals/materials and other resources. Where enhanced care as usual involved any additional consultation with trial participants this was also included in the estimate of costs. All costs are reported in a common price year in each country, in the local currency of the country. No discounting of costs or benefits was used given that the economic analysis only reports results at 3 and 12 month follow up periods.

Primary outcome measure: quality adjusted life years gained

Unlike the effectiveness trials, the primary outcome used in the economic analysis was incremental cost per additional quality adjusted life year (QALY) gained at 3 months post-intervention for PM+ versus ECAU. This is because cost per QALY gained (or similar measure such as Disability Adjusted Life Years Averted) is considered to be the reference case outcome measure for economic evaluation (Feng et al., 2020). The QALY is a metric that can be applied to all conditions, allowing investment, for example in mental health interventions to be compared with very different interventions for other health conditions. It has been applied to studies looking at interventions for refugee mental health (Park et al., 2022). This can then help policy makers and budget holders who want information on how best to make use of funds in a way that helps maximise health benefits. While this type of information is just one factor that policy makers will consider; for instance, reducing inequalities in access to services or in outcomes, as well as containing health system costs will be others, it is used to aid in decision making in many high-income countries that are hosting refugees. The WHO also recommend the use of cost effectiveness evidence to help in priority setting in low and middle income countries (World Health Organization, 2022).

In all of the PM+ and SbS trials the 12-item WHODAS 2.0 (Üstün et al., 2010) which measures functional impairment was collected at baseline, immediately post intervention and at 3 and 12-month follow ups. It covers six domains (cognition, mobility, self-care, getting along, life activities, participation). Items were rated on a 1-5 scale (total range 12-60) with higher scores increased functional impairment.

Our economic analysis then made use of a method developed to map WHODAS2.0-12 scores to disability weights that could then be used to express outcomes in terms of QALYs (Lokkerbol et al., 2021). Using a machine learning approach that study used statistical models to test the performance of different regression techniques, where eight items from the WHODAS2.0-12, in addition to sociodemographic characteristics (age, gender, marital status and education), were mapped onto disability weights created using nationally representative survey data from 14 countries, including Syria, collected as part of the Multi-Country Survey Study on Health and Responsiveness (Üstün et al., 2003). We then used the Syria-specific regression function provided by the authors to calculate disability weights in line with previous economic evaluations studies

that have used transformed WHODAS-2.0-12 data (Nadkarni et al., 2017, Patel et al., 2017, Weobong et al., 2017, Buttorff et al., 2012).

Perfect quality health was assumed to have a value of one with zero representing the utility of death, with total QALYs over the study period calculated using the area under the curve approach. Incremental cost per QALY was not possible to calculate in the EASE study as WHODAS data were not collected, so the economic analysis focuses on a costs and consequences analyses only. This includes a comparison of changes in costs and in wellbeing measured using the 14-item Warwick Edinburgh Mental Wellbeing Scale (WEMWBS) (Tennant et al., 2007). In WEMWBS respondents are asked to indicate which score best describes their thoughts or feelings over the past week on a scale from 1 (none of the time) to 5 (all of the time). A higher total score (14-70) indicates greater positive mental wellbeing.

Statistical and stochastic analysis

Given the skewed distribution of costs, differences in mean costs between the two groups in each trial were compared using bias-corrected and accelerated (BCa) bootstrapping 1000 times. Cost differences and QALY differences between the intervention and comparator groups are also estimated using generalised linear regression models (Park et al., 2022). Incremental cost-effectiveness ratios (ICERs) per additional recovery and improvement without recovery at 3-month follow-up were calculated. As with the effectiveness analyses, our main focus is on reporting results using an intention to treat approach, but complete cases only are also reported. Multiple imputation techniques are used to adjust for missing resource use data, while last observation carried forward was used for missing WHODAS 12 domains in order that these observations can also be transformed into utility weights used to estimate QALYs gained.

Stochastic uncertainty was explored through non-parametric bootstrapping 1000 randomly resampled pairs of costs and outcomes. Cost-effectiveness planes are drawn showing the results of bootstrapping, and indicating the likelihood of being cost effective at country-specific willingness to pay per QALY gained thresholds. Cost-effectiveness acceptability curves (CEACs) are generated to show the likelihood PM+ is cost-effective at different willingness to pay levels. Sensitivity analyses are also conducted to look at how changes in intervention costs or number of participants reached in group interventions, as well as the sustainability of any QALY gains impact on cost-effectiveness results. When reporting full results of the economic analyses this is done in line with the Consensus Health Economic Criteria list (CHEC-list) (Evers et al., 2005).

4.2. PM+ Trials

Trials of PM+ took place in Jordan, the Netherlands, Switzerland and Türkiye. In all settings participants consisted of Arabic-speaking Syrian refugees and asylum seekers experiencing elevated levels of psychological distress. Inclusion criteria were: 1) arrival in host country after the outbreak of the Syrian civil war in 2011, 2) being 18 years or older, 3) having elevated psychological distress (Kessler Screening Scale for Psychological Distress (K 10) > 15) (Kessler et al., 2002), and 4) impaired psychosocial functioning (WHO Disability Assessment Schedule (WHODAS 2.0 > 16) (Üstün et al., 2010). In Jordan, having a child or dependent aged 10-16 living in the household was an additional inclusion criteria (Bryant et al., 2022). Exclusion criteria consisted of having (a) an acute medical condition, (b) an imminent risk of suicide, (c) severe mental disorder (psychotic disorders or substance use dependence), or (d) severe cognitive impairment and e) the inability to follow the study procedures. Participants were also excluded if they received ongoing treatment in specialised mental health care.

Methods of participant recruitment varied depending on country setting. In the Netherlands participants were recruited through community centres, non-governmental organisations, reception centres, language schools and social media. In Türkiye participants were recruited in collaboration with our partner organisation RASASA (Refugees and Asylum Seekers Assistance and Solidarity Association), a non-governmental organisation for refugees in Sultanbeyli, İstanbul, the area in Türkiye where the study took place. This involved placing posters and brochures advertising the study within the RASASA centre. In addition, a video with information on PM+ was projected at the entrance to the RASASA centre. There were also referrals from the protection unit of RASASA. In Jordan, where the study took place in a closed refugee camp, recruitment relied on door-to-door screening of consecutive caravans with only one adult per caravan invited to participate. In Switzerland participants were recruited from refugee and asylum seeker centres, community settings and through local stakeholders in the Arab community, making use of social media (including facebook), television programme on a migrant media network, leaflets, awareness raising at social events and contact with health care professional working with refugees.

Baseline assessment included questionnaires on demographics, clinical scales, daily functioning, stressful events, and health service utilisation (These are set out in detail in other STRENGTHS deliverables). In all settings after baseline assessment, participants were randomised 1:1 into PM+ in addition to care as usual (PM+/CAU) or CAU alone. The outcome assessors were masked to treatment condition allocation. Participants were re-assessed one week, three months and ultimately 12 months after the intervention. The 3-month follow-up assessment was the primary time point for testing the effectiveness of PM+.

Two formats of PM+ were assessed. PM+ can be delivered on a one-to-one (iPM+) basis (Netherlands and Switzerland) or in group format gPM+ formats (Jordan and Türkiye). In both cases it consists of five weekly in-person sessions delivered by Arabic-speaking Syrian non-specialist helpers/facilitators. It integrates four evidence-based behavioural strategies: stress management using diaphragmatic breathing (session 1), problem-solving (session 2), behavioural activation by re-engaging with pleasant/task-oriented activities (session 3), and accessing social support (session 4). Homework practice is scheduled following each session and reviewed in the next session. Psychoeducation is delivered in session 1 and relapse prevention in session 5.

The material and the intervention were linguistically and culturally adapted to the needs of Syrian refugees (Akhtar et al., 2021, Bird et al., 2017) For iPM+ each weekly session was 90 minutes long and delivered by one helper, whilst gPM+ sessions lasted 2 hours and were delivered by 2 facilitators per each group, with each group typically containing between 8 and 12 participants. Due to COVID-19 restrictive measures (first partial lockdown in March 2020), iPM+ participants were given the option for in-person or videocall sessions. The trial in Jordan was not affected by the COVID outbreak, whilst the trial in Türkiye was paused during the COVID outbreak.

The economic analysis, includes an estimate of time, resources and materials used to train individuals to deliver PM+ as well as time spent supervising these individuals. Both helpers (iPM+) and facilitators (gPM+) received 8 days of training followed mainly by weekly (in Switzerland later in the trial this was once a month) face-to-face group supervision by PM+ trainers/supervisors throughout the trials. Training involved education about common mental disorders, basic counselling skills, delivery of intervention strategies and selfcare. Group facilitators received training on basic helping skills, group management skills, gPM+ techniques, the importance of supervision, privacy of the participants, security, and self-care. Supervision included discussion of individual cases and difficulties experienced by helpers, practice of skills and self-care. Trainers/supervisors were mental health care professionals who underwent 5-day training covering elements of the training of helpers, as well as training and supervision skills. In Jordan a local supervisor who worked within the camp provided weekly supervision throughout the trial. The local supervisor also received fortnightly supervision by a primary trainer of gPM+ in Sydney, Australia via Skype.

As noted above, care as usual (CAU) or enhanced care as usual (ECAU) was the comparator in all PM+ trials. In the Netherlands this includes all (mental) health services ranging from primary to specialist mental health care that refugees may access in the Netherlands. For refugees in reception centres this care would be organised by the Central Agency for the Reception of Asylum Seekers [COA] whilst permanent residents would access services in the same way as any other resident and obtain mental health services via their local

general practitioner (primary care doctor). In Switzerland refugees also had access to the health care system and additionally were given a booklet explaining the Swiss health care system in Arabic (Bundesamt für Gesundheit and Staatssekretariat für Migration, 2017). In addition, participants were instructed to contact their general practitioner if they required further mental health assistance.

In Türkiye there is free access to health services in primary health care centres and hospitals for refugees; in addition, all participants received a leaflet with information on community mental health services that were available. In Jordan most usual care would be provided by specialist international organisations within the closed camp, they would only have very limited access to regular Jordanian health care services, for which out of pocket fees might apply. Participants in the enhanced usual care group in Jordan were given specific information about their services in the camp that could assist with the problems identified at baseline assessment. This information included organisations providing services for mental health problems, as well as health, parenting, and vocational training. Sessions were approximately 15 minutes in duration. In the case of Jordan, the economic analysis also estimated the costs of these sessions for the ECAU group.

4.3. Step by Step (SbS) Trials

As well as PM+ the economic analysis is also assessing the economic case for investing in Step by Step (SbS). Face to face delivery of brief psychological services may not always be feasible, and the costs of implementation and scale up may be high in some settings. An alternative approach is online delivery of support. This is where SbS comes in. SbS is a potentially scalable e-mental health intervention approach developed by the WHO for adversity-affected populations (Carswell et al., 2018). It was initially conceptualised as an online self-help version of WHO's Problem Management Plus (PM+) (Carswell et al., 2018). However, it was adapted to focus on 'depression with behavioural activation as the central therapeutic component with additional components covering psychoeducation, stress management techniques (slow breathing), identifying strengths, positive self-talk, increasing social support and relapse prevention' (Carswell et al., 2018).

In STRENGTHS, the original WHO approach for providing SbS was adapted for fully self-guided administration to maximise 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 an in-app messaging system. The intervention was made available for both Apple and Android devices, as well as through a website. The app versions could be freely downloaded from the Google Play and Apple App Stores and intentionally could be used offline, so having constant access to the internet was not a problem.

The implementation of Step by Step (SbS) was evaluated in Egypt, Germany and Sweden. The inclusion criteria were similar to those for the PM+ trials. In addition, they were required to have access to an Apple or Android smartphone/tablet or a computer/laptop with internet connectivity. Suicide-risk was again a reason for exclusion from the trial. Following online baseline assessment, participants were randomised 1:1 into SbS or care as usual.

As this was an online only intervention recruitment was rather different to PM+. In Germany and Sweden there was a reliance on the use of social media, firstly through adverts on Facebook and Instagram, and later through a paid influencer campaign with 12 well-known Arabic influencers. In Alexandria, Egypt, a different strategy was adopted with a local non-governmental organisation inviting eligible Syrians to participate after providing information about the study. Potential participants could then access the app or the web version of SbS directly through posts on social media or on-site with the NGO team's assistance.

Like PM+ SbS also consists of 5 weekly sessions. These 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. All texts are available in Levantine Arabic and English, and is fully audio supported for illiterate users. The e-helper team 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.

Time, materials and other costs associated with training of e-helpers were also considered in the economic analysis. E-helper training 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.

4.4. EASE Trial

In addition to conducting economic evaluations of PM+ and SbS, STRENGTHS is also undertaking an economic analysis of a brief psychological intervention delivered to adolescents, the Early Adolescent Skills for Emotions (EASE) intervention in Lebanon. Deliverable 4.3 and the published trial protocol (Brown et al., 2019) provides detailed information on EASE. In brief it is a WHO-developed intervention intended to address depression and anxiety, as well as other internalising disorders, and is delivered face-to-face over

seven group sessions with adolescents, and three group sessions with their caregivers (Dawson et al., 2019). Sessions are delivered weekly in groups of 6 to 10 and last between 1.5 and 2 hours. The sessions for adolescents involved: psychoeducation about the effects of stressful events, and identifications of emotions (session 1); reducing arousal using relaxation and stress management techniques (i.e. slow breathing) (session 2); behavioural activation strategies (sessions 3 and 4); problem solving strategies, including seeking social support (session 5 and 6); relapse prevention to manage future stressors (session 7). The caregiver sessions involved: psychoeducation and skills to help their child cope with distress (session 1); positive parenting skills, including praise, reducing harsh punishment and promoting communication skills (session 2); strategies to manage caregivers' own stress (e.g. advice about sleep, nutrition, stress reduction exercises, and utilisation of social support) (session 3). During caregiver sessions, another staff member was available to provide child care as necessary.

Participants needed to be aged 10-14, able to attend weekly EASE sessions, screen positive for psychological distress > 12 on the Pediatric Symptom Scale (PSC-17) (Jellinek et al., 1999), and have parent/other family guardian consent. Unlike the other studies in STRENGTHS, participants in Lebanon could be of any nationality and did not have to be refugees. Unaccompanied children, as well as those who were married, at risk of suicide or with significant developmental, cognitive, or neurological impairments were excluded. Following baseline assessments, participants were randomly allocated to either the EASE program or ECAU (following a 1:1.6 ratio). The comparator ECAU intervention consisted of a 30 to 45 minute psycho-education home visit for both child and their caregiver. Recruitment strategies included community awareness sessions, use of social media channels and NGO and United Nations programmes.

EASE facilitators, non-professionals recruited from the communities where the study took place, underwent 8 days of training in intervention delivery, as well as basic counselling and communication skills, group facilitation, child protection, security, and self-care. During the study weekly supervision was offered. Each group was conducted by two facilitators.

5. PM+ Results

5.1. Netherlands

Pilot study

Before proceeding to the main trial an economic evaluation was embedded into a pilot randomised controlled trial (RCT) of individual PM+ (iPM+) with 60 Syrian refugees in Rotterdam, the Netherlands. This pilot was a single-blind, randomised controlled trial (RCT) conducted between 15 May 2018 and 23 April 2019. From an economic perspective the main objective was to assess how well the CSRI was completed, and potentially to revise the instrument for the main trial. We also looked at changes in health care resource use and usual activity between the two groups and conducted an exploratory cost effectiveness analysis. For detailed information the pilot trial see Deliverable 5.3, as well as the peer reviewed paper that was published (de Graaff et al., 2020). As part of the pilot study, we also sourced appropriate unit costs for health care services and other resource use in the Netherlands (See Table N.1). These unit cost were also used subsequently in the definitive trial.

Table N1. Unit costs and sources used for economic analysis in the Netherlands (2018 Euros)

Type of Cost	Unit cost	Unit	Source
Community health worker (assumed to be equivalent to nurse practitioner)	€18	Per consultation	Hakkaart-van Roijen, L, et al 2015
Community-based doctor	€34	Per consultation	Hakkaart-van Roijen, L, et al 2015
Psychiatrist	€98	Per consultation	Hakkaart-van Roijen, L, et al 2015
Psychologist	€67	Per consultation	Hakkaart-van Roijen, L, et al 2015
Psychiatric Nurse	€18	Per consultation	Hakkaart-van Roijen, L, et al 2015
Social Worker (maatschappelijk werk)	€68	Per consultation	Hakkaart-van Roijen, L, et al 2015
Physiotherapist	€34	Per session	Hakkaart-van Roijen, L, et al 2015
Other health professionals (assumed same as community health worker)	€18	Per consultation	Hakkaart-van Roijen, L, et al 2015
Inpatient Psychiatric Stays	€316	Per day	Hakkaart-van Roijen, L, et al 2015
Hospital Inpatient Stays - General health (weighted average for general and university hospitals)	€495	Per day	Hakkaart-van Roijen, L, et al 2015
Hospital Outpatient Services - General health (weighted average for general and university hospitals)	€95	Per visit	Hakkaart-van Roijen, L, et al 2015
Hospital A&E	€269	Per visit	Hakkaart-van Roijen, L, et al 2015
Medications (Tramadol)	€0.04	Per 50mg capsule	Zorginstituut Nederland
Medications (Duloxetine)	€0.06	Per 30 mg capsule	Zorginstituut Nederland
Medications (Citalopram)	€0.03	Per 20mg tablet	Zorginstituut Nederland
Medications (Paroxetine)	€0.05	Per 20mg tablet	Zorginstituut Nederland
Medications (Hydroxytryptophan)	€1.11	Per 50mg capsule	Zorginstituut Nederland
Medications (Oxazepam)	€0.02	Per 10mg tablet	Zorginstituut Nederland
Medications (Diazepam)	€0.05	Per 10mg tablet	Zorginstituut Nederland
Medications (Haloperidol)	€0.05	Per 1mg tablet	Zorginstituut Nederland
Medications (Mirtazapine)	€0.05	Per 15mg tablet	Zorginstituut Nederland
Medications (Quetiapine)	€0.04	Per 25mg tablet	Zorginstituut Nederland
Medications (Sertraline)	€0.07	Per 100mg tablet	Zorginstituut Nederland
Medications (Fluoxetine)	€0.05	Per 20mg capsule	Zorginstituut Nederland
Medications (Melatonin)	€0.07	Per 3mg tablet	Zorginstituut Nederland
Medications (Zopiclon)	€0.04	Per 7.5mg tablet	Zorginstituut Nederland
Medications (Lamotrigine)	€0.15	Per 200mg tablet	Zorginstituut Nederland
Medications (Valproate - Depakine Chrono)	€0.14	Per 250mg tablet	Zorginstituut Nederland
Medications (Xanax)	€0.13	Per 0.5mg tablet	Zorginstituut Nederland

Medications (Paliperidone) Invega version	€5.03	Per 9mg tablet	Zorginstituut Nederland
Medications (Amitriptyline HCL)	€0.04	Per 25mg tablet	Zorginstituut Nederland
Medications (Topiramate)	€0.05	Per 25mg tablet	Zorginstituut Nederland
Medications (Temazepam)	€0.05	Per 10mg tablet	Zorginstituut Nederland
Medications (Nortriptyline RIA)	€0.10	Per 25mg tablet	Zorginstituut Nederland
Medications (Levocetirizine)	€0.03	Per 5mg tablet	Zorginstituut Nederland
Minimum wage rate aged 20 (July 2018)	€51.51	Per day	Govt of the Netherlands
Minimum wage rate aged 21 (July 2018)	€63.39	Per day	Govt of the Netherlands
Minimum wage rate aged 22+ (July 2018)	€74.58	Per day	Govt of the Netherlands

Using the CSRI we were able to identify that there were no significant group differences in health service or productivity costs at baseline between PM+/CAU and CAU. At 3-month follow-up mean costs per PM+/CAU participant in the PM+/CAU group from a health care perspective were significantly higher than in the CAU group participants from a health service perspective (€888.75 [SD €432.24] vs €347.97 (326.93); MD, €540.78; 95% CI, €332.20 to €749.35, $p=.000$) (Table N2). Excluding costs of PM+ training, supervision and delivery of PM+, costs remained non-significantly higher for in the PM+/CAU group, but this cost difference was no longer significant (€485.65 [€432.24] vs €347.97 (326.93); MD, €137.67; 95% CI, €-72.85 to €348.21, $p=.191$). Productivity costs were non-significantly lower in the PM+/CAU arm but this difference was not significant (€28.91 [102.78] vs €297.15 [894.29]; MD €268.24 95% CI, €-631.22 to €94.73, $p=.141$). There was no significant difference in overall costs, including both health and productivity losses, between PM+/CAU and CAU.

In the pilot study we also undertook an exploratory cost-effectiveness analysis, in this case because of the small sample the outcome used in the economic analysis was additional recovery achieved (Table N3). From a health system perspective iPM+ had an incremental cost per additional recovery achieved of €5,047, (95% CI €0, €19,773). This reduced to €2,266 (95% CI €-1,070, €15, 930) when productivity losses averted were included. In sensitivity analysis involving parametric bootstrapping with random sampling of 1,000 pairs of costs and outcomes, iPM+ may even have both better outcomes and lower costs than CAU. While no accepted cost-effectiveness threshold for recovery from depression and anxiety exists, the cost effectiveness acceptability curve (CEAC) indicated at least an 85% chance that PM+/CAU would be cost-effective if funders were willing to pay €10,000 per recovery achieved.

In our costing analysis for the pilot study no significant difference in health service utilisation or costs was observed between groups, but overall costs were significantly higher in the iPM+ group due to PM+ implementation costs. Mean intervention costs ultimately are likely to be lower if trainers and helpers can be retained and continue to deliver iPM+ to more refugees over a longer time period. Nonetheless, our exploratory economic analysis suggested PM+ has the potential to be cost effective from a health system perspective.

Table N.2. Mean health and productivity costs (2018 Euros) per pilot study participant at 3 month follow up

Type of Cost	PM+/CAU (n=28)	CAU (n=26)	Mean Difference (BCa 95% CI)	p
PM+ Intervention Costs				
PM+ Intervention (SD)	403.10 (0)	0 (0)	403.10 (403.10, 403.10)	0.000
Health Service Cost, <u>Mean</u> (SD)				
Community health worker	5.14 (12.83)	2.08 (5.86)	3.07 (-1.64, 8.63)	0.260
Community-based doctor	61.93 (79.63)	51.00 (90.85)	10.93 (-38.36, 56.03)	0.641
Psychiatrist	45.50 (129.25)	18.85 (55.57)	26.65 (-15.59, 86.93)	0.325
Psychologist	35.89 (155.25)	10.31 (41.05)	25.59 (-16.75, 91.12)	0.407
Psychiatric Nurse	0.00 (0.00)	3.46 (12.49)	-3.46 (-9.00, 1.24)	0.135
Social Worker	99.57 (192.76)	94.15 (150.31)	5.42 (-83.66, 96.26)	0.908
Physiotherapist	78.93 (205.27)	40.54 (125.76)	38.39 (-44.74, 138.50)	0.408
Other health professionals	90.64 (58.27)	96.23 (58.92)	-5.59 (-36.95, 27.78)	0.728
Hospital Inpatient Stays - General health	35.36 (187.09)	0.00 (0.00)	35.36 (-29.12, 134.97)	0.139
Hospital Outpatient Services - General health	30.54 (58.12)	25.58 (78.60)	4.96 (-36.28, 41.64)	0.795
Medications	2.15 (8.33)	5.78 (15.81)	-3.63 (-11.29, 3.23)	0.303
Total Health Service Utilisation Costs	485.65 (432.24)	347.97 (326.93)	137.67 (-67.71, 355.53)	0.195
Total Health System Costs, <u>M</u> (SD)				
	888.75 (432.24)	347.97 (326.93)	540.78 (336.17, 755.78)	0.001
Productivity losses, <u>M</u> (SD)				
	28.91 (102.78)	297.15 (894.29)	-268.24 (-719.91, 6.76)	0.325
Total Health and Productivity Costs, <u>M</u> (SD)				
	917.65 (453.28)	645.12 (1149.46)	272.53 (-338.81, 711.02)	0.368

Table N3. Results of exploratory cost effectiveness analyses for pilot study at 3 month follow up

	Health system perspective	Likelihood cost-effective	Health system and productivity loss perspective	Likelihood cost-effective
Incremental cost per recovery achieved at 3-month follow-up (95% CI)*	€5,047 (€0, €19,773)	85%	€2,266 (€ -1,070, €15,930)	93%
Incremental cost per improvement achieved at 3month follow-up (95% CI)**	€2,009 (€0, €2406)	93%	€902 (€-276, €1,813)	98%

*Assumes a willingness to pay of €10,000 per recovery on the HSCL-25 achieved; **assumes a willingness to pay of €2,000 per significant improvement on the HSCL-25 achieved

Economic evaluation alongside definitive trial

After successful implementation of the pilot RCT, we conducted an economic evaluation alongside a fully-powered RCT of iPM+ plus CAU compared to CAU only with 206 Syrian refugees in the Netherlands. Participants were enrolled between March 2019 and December 2021. The trial reported significant positive impacts on primary effectiveness outcomes concerning depression and anxiety at 3 month follow up. Full details of the study and participant characteristics are reported elsewhere (Deliverable 5.3). Here we briefly set out the headline findings of our economic analysis. We only provide limited information on these findings in this version of the report; a more extensive version of the report with these findings will be available from the authors once the results have been accepted for publication.

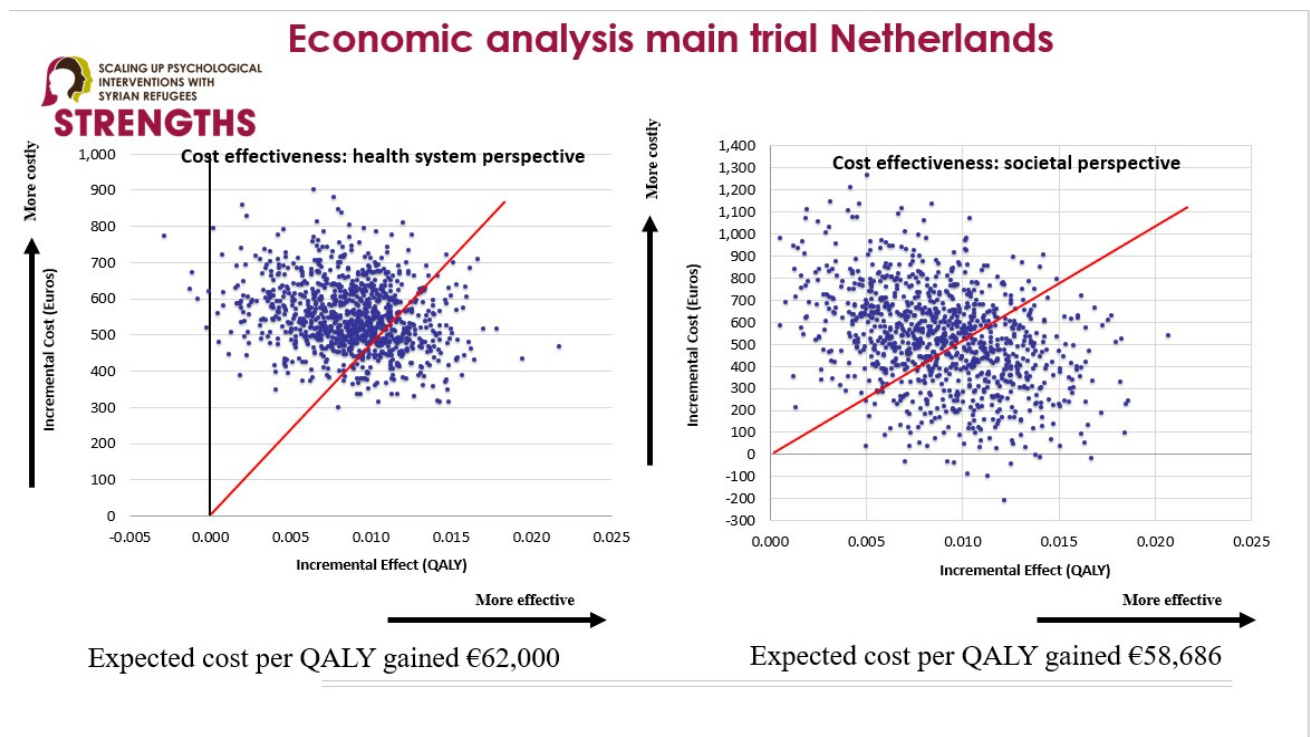
In short, the results of our cost effectiveness analysis at 3 month follow up suggest that there is a promising case for investment in iPM+ where the impact on quality of life is considered. This economic case is further strengthened by the significantly better positive clinical outcomes observed in study. In the effectiveness analysis WHODAS scores were more favourable in the iPM+ group, although this difference was not significant. In the economic analysis when we transformed WHODAS scores into utility values used to calculate changes in quality of life, at 3 month follow up we found a small but significant effect (Cohens-d 0.376, p= 0.014) with greater increase in QALYs gained in the iPM+ group.

Turning to service utilisation there were very few significant differences in resource utilisation or in the costs of service utilisation between the two trial groups at any of the three time points. Table N4 shows changes in service utilisation between the two groups at three month follow up. iPM+ participants spent significantly more time in consultation with primary care doctors compared to the CAU group (mean difference 19.15 minutes, $p = 0.044$). This might hopefully suggest that, with greater levels of contact time with primary care doctors, health problems may be detected earlier leading to lower future health service costs. Overall, the mean costs at 3 month follow up were significantly greater for the iPM+ group, but this was entirely due to the implementation costs of the intervention. The cost per QALY gained from a health system perspective is €62,000.

Table N.4. Main study: mean service utilisation/ days out of role at 3 month follow up

Type of Contact	PM+ N=103	ECAU N=103	Mean Difference (BCa 95% CI)	P
Health Service Utilisation, <u>M</u> (<u>SD</u>)				
Community health worker (minutes)	5.44 (24.00)	5.26 (42.82)	0.18 (-12.13, 9.39)	0.970
Community-based doctor (minutes)	36.89 (74.90)	17.73 (28.34)	19.15 (4.48, 35.77)	0.046
Psychiatrist (minutes)	11.17 (44.36)	2.35 (12.50)	8.82 (-0.79, 18.49)	0.109
Psychologist (minutes)	22.22 (99.21)	17.65 (103.85)	4.57 (-25.88, 34.28)	0.758
Psychiatric Nurse (minutes)	3.33 (22.68)	1.02 (6.81)	2.31 (-1.55, 8.55)	0.360
Social worker (minutes)	14.00 (83.07)	18.27 (91.23)	-4.27 (-28.82, 19.93)	0.738
Physiotherapist (minutes)	132.67 (950.36)	35.96(122.86)	96.70 (-22.28, 323.92)	0.464
Home care (minutes)	0.00 (0.00)	0.91 (6.75)	-0.92 (-2.27, 4.34)	0.181
Other care (minutes)	0.00 (0.00)	1.22 (12.12)	-1.22 (-3.65, 1.21)	0.320
Psychiatric inpatient stay (nights)	0.00 (0.00)	0.11 (1.01)	-0.11 (-0.32, 0.09)	0.373
Other inpatient stay (nights)	0.17 (0.91)	0.16 (1.42)	0.00 (-0.35, 0.35)	0.984
Hospital Emergency Department (contact)	0.06 (0.23)	0.05 (0.30)	0.00 (-0.07, 0.08)	0.907
Psychiatric outpatient (contact)	0.00	0.00	0.00	
Other outpatient (contact)	1.29 (3.66)	0.81 (1.67)	0.48 (-0.35, 1.32)	0.254
Medications (Doses)	12.53 (44.71)	6.96 (38.85)	5.57 (-5.53, 17.02)	0.365
CAM (minutes)	1.58 (10.06)	1.34 (10.51)	0.24 (-2.89, 3.34)	0.907
All community (minutes)	227.30 (989.90)	101.72 (227.87)	125.58 (-10.88, 340.91)	0.430
All hospital contacts/visits	1.51 (3.96)	1.13 (3.13)	0.38 (-0.66, 1.37)	0.498
Productivity Loss (days)	5.03 (23.62)	3.48 (14.81)	1.55 (-3.31, 7.57)	0.633

To address uncertainty in our economic findings we undertook non-parametric bootstrapping. Figure N1 shows two cost effectiveness planes from the health system and societal perspectives showing 1,000 randomly sampled pairs of outcomes and costs drawn from the trial. In nearly all cases costs of iPM+ are greater than ECAU, but QALY gains are generally positive, being to the right of zero on the X axis. The red line represents a cost per QALY gained threshold of €50,000. If this is deemed to be an acceptable cost effectiveness threshold then 29% and 41% of the combinations of cost and outcomes lie below this threshold from the health and societal perspectives. Although these are both relatively low chances of being cost effective, reductions in the costs of helper training and supervision over time will improve this cost effectiveness ratio. If some of the QALY gains are sustained beyond the 3 month follow up then cost effectiveness will also be strengthened. This will be assessed when 12 month follow up data are available. If different outcome measures, such as recovery achieved are used instead then a positive economic case can also be presented.



5.2. Jordan

An economic evaluation was undertaken alongside the definitive RCT in Jordan. This trial of gPM+ enrolled 410 refugees; 204 refugees randomised to to gPM+ and 206 to ECAU. Full details on this trial are available in Report D4.3, as well as in a journal publication (Bryant et al., 2022). The setting for the trial in Jordan is a closed (secure) refugee camp, the Azraq Refugee Camp. Azraq is the second largest camp located in the desert near the city of Azraq with a population of 36,657 Syrians (as of June, 2020) of which 61% are children. Due to high levels of camp security, internet access is limited as is internal and external mobility.

We began by designing iteratively a version of the CSRI to collect health and other service use data. Given the lack of work opportunities within the refugee camp, we did not collect information on time out of work and therefore our economic analysis was only conducted from the perspectives of health service funders and participants. We also sourced appropriate unit costs for health services in a Jordanian context; these are shown in Table J1.

Table J1 Health service unit costs and sources (Jordanian Dinars 2020)

Type of Cost	Unit cost (JD)	Unit	Source and assumptions
Community health worker (contact)	35.72	Per hour	Average unit cost of visit to a MoH health centre. Halasa-Rappel 2020. Visit 15 minutes
Community-based doctor (contact)	35.72	Per hour	Average unit cost of visit to a MoH health centre. Halasa-Rappel 2020. Visit 15 minutes
Traditional practitioner	35.72	Per hour	Assumed same as average unit cost of visit to a MoH health centre. Halasa-Rappel 2020. Visit 15 minutes
Psychiatrist (contact)	36.13	Per hour	Mid-range hourly cost of consultant medical professional. Hammad et al 2022
Psychologist (contact)	36.13	Per hour	Mid-range hourly cost of consultant medical professional. Hammad et al 2022
Social worker (contact)	35.72	Per hour	Assumed same as cost of contact with health care worker Average unit cost of visit to a MoH health centre. Halasa-Rappel 2020. Visit 15 minutes
Other inpatient stay (nights)	242.52	Per night	Average cost per inpatient day in publicly funded hospitals. Hammad et al 2022
Hospital Emergency Department (contact)	32.60	Per contact	Average cost per emergency room visit in publicly funded hospitals. Hammad et al 2022
Amitriptyline hydrochloride	1.96	Per month	Public sector price for generic for one months treatment 25mg 3 times per day Alefan et al 2018
Respirox	3.03	Box of 20	Pharmacy Price for Box of 20 Jordan 25/5/2020. Source Jordan Food and Drug Administration via MedicaRCP.com
Respal	3.46	Box of 20	Pharmacy Price for Box of 20 Jordan 17/3/2021. Source Jordan Food and Drug Administration via MedicaRCP.com

Although not formally piloted in the Jordanian study, the CSRI was field tested and found to be easy to complete. We then proceeded to undertake economic analysis upon completion of the trial and here briefly set out the headline findings of our economic analysis. We only provide limited information on these findings in this version of the report; a more extensive version of the report with these findings will be available from the authors once the results have been accepted for publication. This includes findings on the 12 month follow up analyses.

In short, the results of our cost effectiveness analysis at 3 month follow up suggest that there is a potential case for investment in gPM+ where the impact on quality of life is considered as the primary outcome. This, however, is likely to be dependent on reducing some of the costs associated with gPM+ implementation, and we recognise that implementation costs here were high due to the nature of the trial setting, a closed camp located a considerable distance away from where local service delivery partners are based.

The definitive trial reported significant greater reductions in depression scores in the gPM+ group compared to ECAU at 3 month follow up. It also reported that more participants in the gPM+ arm relative to EUC achieved a minimally important difference between baseline and 3-month follow-up for WHODAS (gPM+ 76.2%, EUC 66.1%); χ^2 6.67, $p=0.04$). In the economic analysis when we transformed WHODAS scores into utility values used to calculate changes in quality of life, at 3 month follow up we found a small but significant effect (Cohens-d 0.196, $p= 0.049$) with a greater increase in QALYs gained in the gPM+ group.

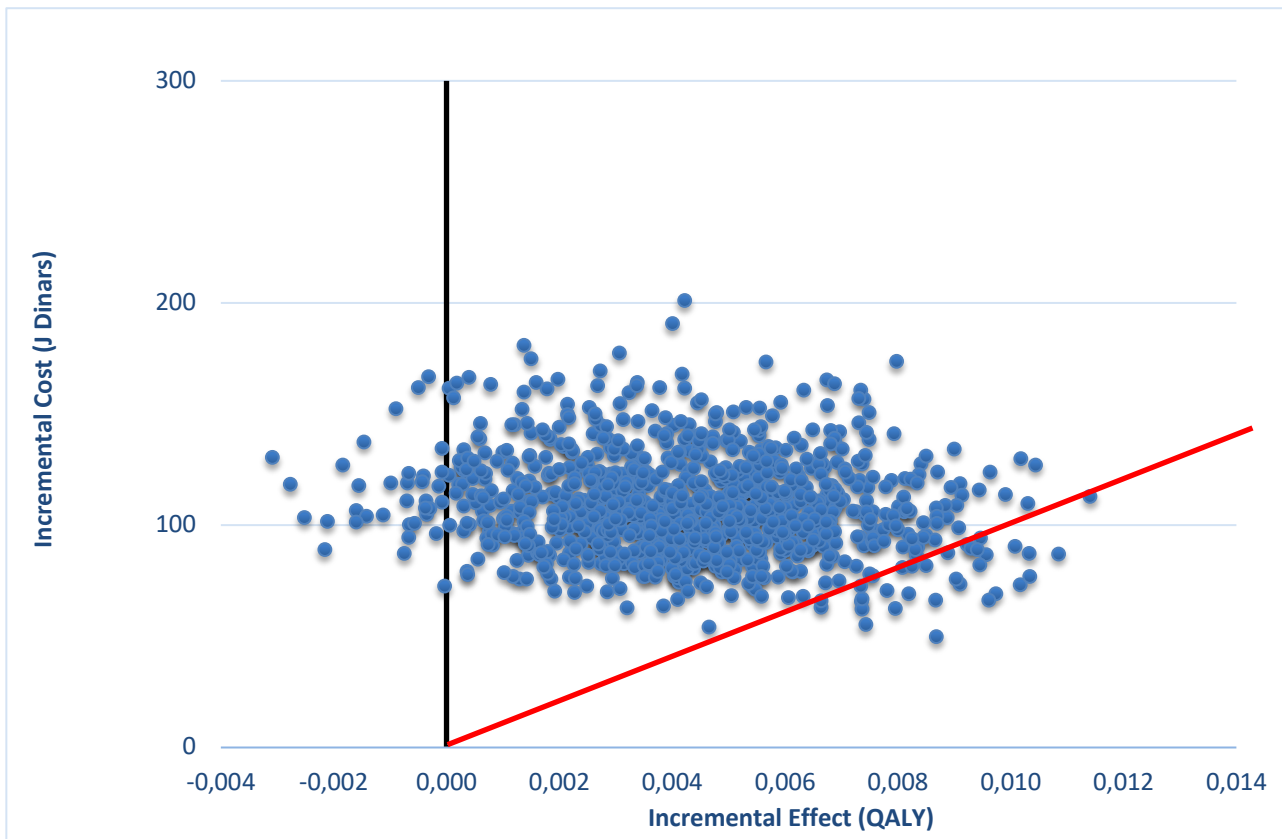
Turning to service utilisation there were no significant differences in resource utilisation or in the costs of service utilisation between the two trial groups at any of the three time points. Table J2 shows changes in service utilisation between the two groups at three month follow up. One observation is the very low level of any service usage; there was very little use of mental health services in either group, reflecting the very limited access to these services within the camp. Use of services within the Jordanian health system outside of the camp could incur out of pocket fees. Overall, the mean costs at 3 month follow up were significantly greater for the iPM+ group, but this was entirely due to the implementation costs of the intervention. The cost per QALY gained is approximately 36,000 Jordanian Dinars. There is no formal accepted cost effectiveness threshold in Jordan, but it is more likely to be less than 10,000 Dinars.

To address uncertainty in our findings we undertook non-parametric bootstrapping. Figure J1 shows a cost effectiveness plane showing 1,000 randomly sampled pairs of outcomes and costs drawn from the trial. In all cases costs of gPM+ are greater than ECAU, but QALY gains are generally positive, with most being to the right of zero on the X axis. The red line represents a cost per QALY gained threshold of 9,115 Jordanian Dinars, which is 3 times GDP per capita in Jordan. In our analysis there is less than a 10% chance that gPM+ would be considered cost effective. However, implementation of the intervention within the closed refugee camp is expensive. If training and implementation costs could be lower in future as training of trainers and other training support are less needed, then the probability of being considered cost effective will be improved. For instance, in sensitivity analysis where costs of training and delivery could be halved and quality of life gains sustained for a further three months then the probability of being considered cost effective within a Jordanian context rises to 70%.

Table J2: Mean Difference in Cumulative Service Utilisation Per Participant at 3-Month Follow-Up

Type of Contact	PM+ N=206	ECAU N=204	Mean Difference (BCa 95% CI)	P
Health Service Utilisation, <u>M</u> (<u>SD</u>)				
Community health worker (minutes)	3.27 (14.76)	3.50 (15.06)	-0.23 (-3.83, 3.00)	0.899
Community-based doctor (minutes)	25.95 (48.80)	23.94 (36.28)	2.01 (-6.49, 11.12)	0.658
Psychiatrist (minutes)	0.34 (2.82)	0.43 (4.45)	-0.09 (-0.91, 0.61)	0.827
Psychologist (minutes)	0.00 (0.00)	0.23 (3.21)	-0.23 (-0.68, 0.22)	0.132
Social worker (minutes)	0.00 (0.00)	1.07 (10.66)	-1.07 (-2.56, 0.43)	0.065
Psychiatric inpatient stay (nights)	0.00 (0.00)	0.00 (0.00)		
Other inpatient stay (nights)	0.18 (1.08)	0.09 (0.40)	0.09 (-0.08, 0.26)	0.290
Hospital Emergency Department (contact)	0.46 (1.29)	0.53 (2.11)	-0.07 (-0.42, 0.28)	0.695
Psychiatric outpatient (contact)	0.00 (0.00)	0.00 (0.00)		
Other outpatient (contact)	3.52 (11.90)	4.52 (18.93)	-1.00 (-4.47, 1.72)	0.530
Medication (Doses)	1.04 (13.76)	0.92 (12.97)	0.12 (-2.56, 3.14)	0.925
CAM (contacts)	0.01 (0.11)	0.01 (0.07)	0.01 (-0.01, 0.03)	0.505
All community contacts (minutes)	33.10 (60.70)	33.70 (57.71)	0.60 (-12.46, 11.78)	0.925
All hospital contacts/visits	0.65 (1.81)	0.62 (2.23)	0.02 (-0.44, 0.45)	0.919

Figure J1: Cost effectiveness plane at 3 month follow up Jordan: health system perspective



The cost effectiveness plane shows 1,000 bootstrapped randomly sampled pairs of cost and outcomes

5.3. Türkiye

Pilot study

The economic analysis started with work to design and pilot a modified version of the CSRI, adapted to the Turkish context, as part of a randomised controlled pilot trial with 46 community dwelling Syrian refugees of group PM+ (gPM+). Our CSRI recorded information on the frequency and duration of service contacts; appropriate unit costs for services in Türkiye were then attached to estimate health system costs from the perspective of the publicly funded health insurance system, in addition to productivity costs to society valued using the Minimum Wage Determination Commission set national minimum wage in 2020. The CSRI was well-completed and we were able to analyse resource use and attach appropriate unit costs to these costs. Unit costs to attach to resource use were sourced iteratively and have been used for the pilot and subsequent main trial study (See Table T1).

As part of the economic analysis in the pilot study, mean differences in the economic costs and use of health services, as well as in productivity losses between baseline and 3-month follow up between the two groups were analysed and uncertainty in cost distribution was accounted for using bias-corrected and accelerated bootstrapping. Service utilisation in both groups was very low (See Table T2). The analysis also revealed that there was no significant difference in overall cost between the two groups nor in any single element of costs to the health system or productivity losses (See Table T3). The pilot study though was not intended to be powered to detect any significant difference between arms. Full details on the results of the pilot study including the economic analysis have been published (Acarturk et al., 2022). In addition, we also found that in the pilot study that there was no significant change in quality of life scores in either the gPM+ or CAU groups.

Table T1. Unit costs (2020 Turkish Lira)

Type of Cost	Unit cost	Unit	Source and assumptions
Community health worker (contact)	39.77	Per hour	Sourced from Pratisyen Hekim 15 Şubat Maaşları !Assume low scale point circa 7000 TL [General practitioner salaries Feb 2020] https://www.saglikpersoneli.com.tr/gundem/pratisyen-hekim-15-subat-maaslari-h4938.html
Community-based doctor (contact)	39.77	Per hour	Sourced from Pratisyen Hekim 15 Şubat Maaşları !Assume low scale point circa 7000 TL [General practitioner salaries Feb 2020] https://www.saglikpersoneli.com.tr/gundem/pratisyen-hekim-15-subat-maaslari-h4938.html

			pratisyen-hekim-15-subat-maaslari-h4938.html
Psychiatrist (contact)	13.00	Per consultation	Sosyal Güvenlik Kurum [Social Security Institution] tariff for individual psychotherapy consultation
Psychologist (contact)	13.00	Per consultation	Sosyal Güvenlik Kurum [Social Security Institution] tariff for individual psychotherapy consultation
Psychiatric Nurse (contact)	31.25	Per hour	Range between 5,000TL and 6,000TL per month depending on experience; assume 5,500 TL per month
Social worker (contact)	31.25	Per hour	Range between 5,000TL and 6,000TL per month depending on experience; assume 5,500 TL per month
Psychiatric inpatient stay (nights)	109.00	Per night	Sosyal Güvenlik Kurum [Social Security Institution] tariff for inpatient stays for patients in category 2 of tariff code, including PTSD. F32.1 Moderate depressive episode; F33.1 Recurrent depressive disorder, current episode moderate; F34.0 Cyclothymia; (F40-48) Neurotic, stress-related and somatoform disorders (except for code groups F40, F45, F48); F50 Eating disorders; (F60-69) Adult personality and behavioural disorders; (F70-79) Mental retardation; F80 Speech and language specific developmental disorders; F84 Pervasive developmental disorders; F90 Hyperkinetic disorders; F91 Behavioural disorders; F92 Behavioural and emotional mixed type disorders
Other inpatient stay (nights)	30.00	Per night	Sosyal Güvenlik Kurum [Social Security Institution] tariff for standard non-mental health inpatient stays
Hospital Emergency Department (contact)	15.00	Per contact	Sosyal Güvenlik Kurum [Social Security Institution] tariff for standard non-mental health inpatient stays
Psychiatric outpatient (contact)	13.00	Per contact	Sosyal Güvenlik Kurum [Social Security Institution] tariff for individual psychotherapy consultation
Other outpatient (contact)	13.00	Per contact	Varies depending on speciality; we assume here same as SGK tariff for psychiatric outpatient contact
Day Hospital (Visit)	6.00	Per visit	Sosyal Güvenlik Kurum [Social Security Institution] tariff
Policlinic (Visit)	15.00	Per visit	Sosyal Güvenlik Kurum [Social Security Institution] tariff
Productivity Losses	106	Per day	Minimum Wage Determination Commission = 2324 TL per month; assume 22 working days per month = 106 TL per day

Table T2. Mean (SD) service utilisation Turkish pilot study (complete cases only)

Service (unit of measurement)	Baseline		Post-assessment		3 MFU	
	PM+ (n=24)	ETAU (n=22)	PM+ (n=24)	ETAU n=21)	PM+ (n=20)	ETAU (n=20)
Community health worker (contact)	0.04 (0.20)	0.36 (1.34)	0.00	0.05 (0.21)	0.08 (0.41)	0.36 (0.79)
Community-based doctor (contact)	0.96 (2.54)	0.59 (1.05)	0.25 (1.03)	0.23 (1.06)	0.50 (1.29)	0.86 (1.58)
Psychiatrist (contact)	0.00	0.91 (4.26)	0.00	0.05 (0.21)	0.42 (2.04)	0.00
Psychologist (contact)	0.00	0.00	0.00	0.00	0.04 (0.20)	0.00
Psychiatric Nurse (contact)	0.00	0.00	0.00	0.00	0.00	0.00
Social worker (contact)	0.00	0.05 (0.21)	0.00	0.00	0.00	0.09 (0.43)
Psychiatric inpatient stay (nights)	0.00	0.00	0.00	0.00	0.00	0.09 (0.43)
Other inpatient stay (nights)	0.25 (1.22)	0.05 (0.21)	0.92 (4.07)	1.32 (4.02)	0.08 (0.28)	0.23 (0.53)
Hospital Emergency Department (contact)	0.25 (0.74)	0.55 (2.13)	0.29 (0.91)	0.00	0.00	0.77 (2.78)
Psychiatric outpatient (contact)	0.00	0.00	0.00	0.05 (0.21)	0.00	0.00
Other outpatient (contact)	1.29 (2.74)*	0.09 (0.43)*	0.00	0.00	0.54 (1.91)	0.14 (0.47)
Day Hospital (Visit)	0.00	0.68 (1.86)	0.42 (2.04)	0.00	0.00	0.59 (2.56)
Policlinic (Visit)	0.29 (1.08)	0.36 (1.50)	0.29 (1.08)	0.36 (1.50)	0.17 (0.64)	0.45 (1.47)
Medicine (doses)	7.58 (37.15)	0.00	3.79 (18.57)	0.00	3.96 (18.97)	13.00 (59.57)
CAM (contact)	0.42 (1.47)	0.18 (0.59)	0.00	0.00	0.00	0.14 (0.64)
Productivity Loss (days)	8.71 (19.00)	2.55 (6.72)	6.04 (8.89)	12.36 (50.89)	0.54 (1.44)	3.50 (10.37)

Table T3: Pilot Study Mean Difference in Cumulative Costs Per Participant at 3-Month Follow-Up (complete cases only)

Type of Cost	PM+	ETAU	Mean Difference (BCa 95% CI)	p
Cost (Turkish Lira), <u>Mean</u> (SD)				
Community health worker (contact)	0.83 (4.06)	1.51 (3.19)	-0.68 (-2.84, 1.48)	0.530
Community-based doctor (contact)	8.15 (22.35)	27.42 (74.38)	-19.27 (-55.58, 6.49)	0.292
Psychiatrist (contact)	5.42 (26.54)	0.59 (2.77)	4.83 (-1.63, 17.18)	0.334
Psychologist (contact)	0.54 (2.65)	0.00	0.54 (-0.58, 1.66)	0.135
Psychiatric Nurse (contact)	0.00	0.00	0.00	N/A
Social worker (contact)	0.00	1.65 (7.77)	-1.66 (-5.83, 1.79)	0.107
Psychiatric inpatient stay (nights)	4.54 (22.25)	9.91 (46.48)	-5.36 (-29.72, 11.86)	0.626
Other inpatient stay (nights)	30.00 (121.94)	46.36 (125.83)	-16.36 (-91.22, 52.00)	0.657
Hospital Emergency Department (contact)	4.38 (13.62)	11.59 (41.64)	-7.22 (-28.00, 6.57)	0.445
Psychiatric outpatient (contact)	0.00	0.59 (2.77)	-0.59 (-1.82, 0.64)	0.118
Other outpatient (contact)	7.04 (24.84)	1.77 (6.08)	5.27 (-1.60, 14.77)	0.323
Day Hospital (Visit)	2.50 (12.25)	3.55 (15.34)	-1.05 (-10.63, 7.36)	0.801
Policlinic (Visit)	6.88 (18.23)	12.27 (30.23)	-5.40 (-21.53, 9.80)	0.473
Medicine (doses)	0.00	0.00	0.00	N/A
CAM (contact)	0.00	0.00	0.00	N/A
Productivity Loss (days)	697.83 (989.40)	640.82 (1565.23)	57.02 (-784.42, 791.45)	0.885
Total cost	768.10 (1009.66)	758.04 (1664.18)	10.07 (-861.28, 776.25)	0.973

Economic evaluation alongside definitive trial

The main RCT commenced in August 2019 and 368 participants had been enrolled by the time of the COVID-19 pandemic. Further details on the trial, participant characteristics and effectiveness results are available in Deliverable D5.4. As noted in the final report on the trial in Türkiye, pandemic restrictions halted gPM+ sessions until the autumn of 2020, thus delaying the completion of the trial and follow up assessments. Here we briefly set out the headline findings of our economic analysis. We only provide some limited information on these findings in this version of the report; a more extensive version of the report with these findings will be available from the authors once the results have been accepted for publication.

In short, the results of our cost effectiveness analysis at 3 month follow up suggest that there is a promising case for investment in gPM+ if the impact on quality of life is considered. This positive outcome is consistent with the effectiveness analysis which noted that while no significant between-group differences between the

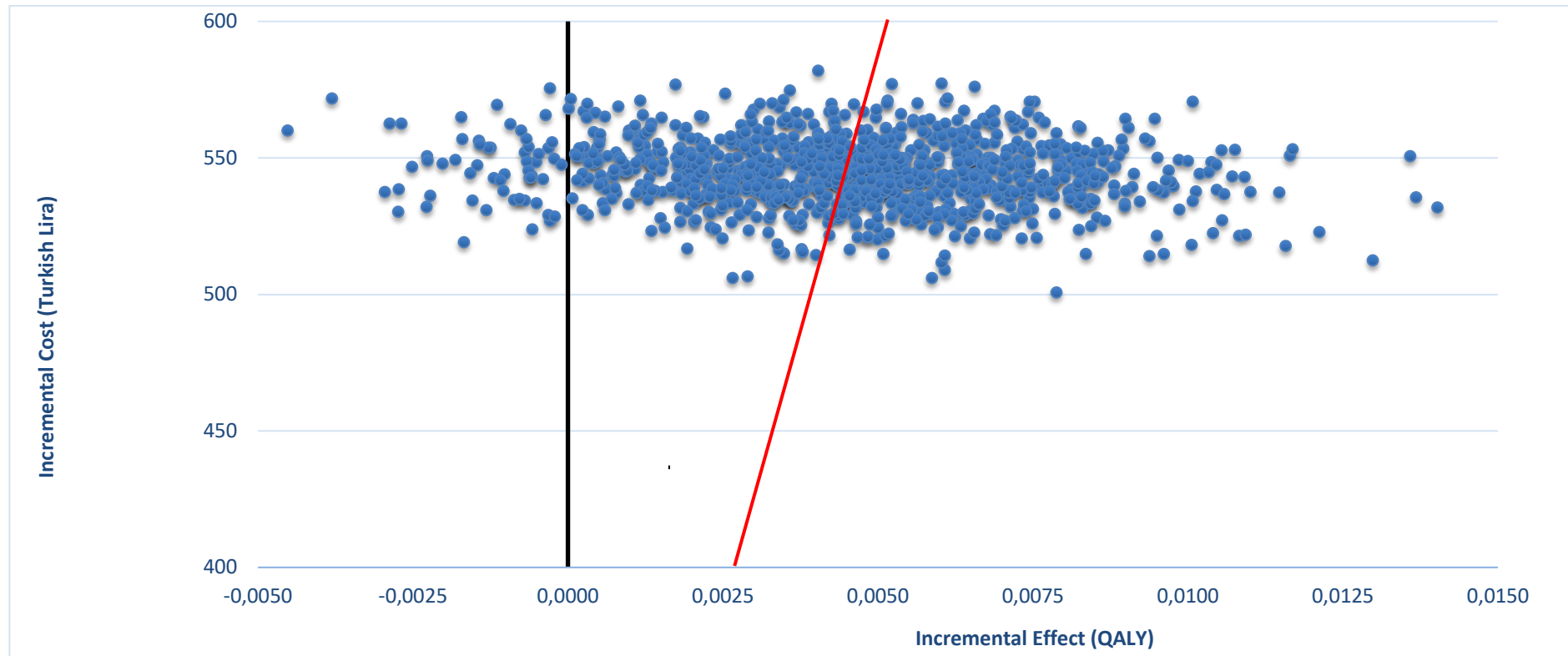
intervention and the control groups in the primary effectiveness trial outcome measures were seen, there was a significant difference in WHODAS scores at 3-month follow-up. In the economic analysis when we transformed WHODAS scores into utility values used to calculate changes in quality of life, at 3 month follow up we also found a small but significant effect (Cohens-d 0.213, p= 0.048) greater increase in QALYs gained in the gPM+ group.

Turning to service utilisation there were no significant differences in resource utilisation or in the costs of service utilisation between the two trial groups at any of the three time points. Table T4 shows changes in service utilisation between the two groups at three month follow up. Overall, the mean costs at 3 month follow up were significantly greater for the gPM+ group, but this was entirely due to the implementation costs of the intervention. To address uncertainty in our findings we undertook non-parametric bootstrapping. Figure T1 shows a cost effectiveness plane showing 1,000 randomly sampled pairs of outcomes and costs drawn from the trial. In all cases costs of gPM+ are greater than ECAU, but QALY gains are generally positive, being to the right of zero on the X axis. The red line represents a cost per QALY gained threshold of 160,000 Turkish Lira. This is equivalent to GDP per capita in Türkiye. If this is deemed to be an acceptable cost effectiveness threshold, then 65% of the combinations of cost and outcomes lie below this threshold and the intervention has a 65% chance of being cost effective. The cost-effectiveness acceptability curve shown in Figure T2 also shows the likelihood of being cost effective at different levels of willingness to pay.

Type of Contact	PM+ N=168	ECAU N=168	Mean Difference (BCa 95% CI)	P
Health Service Utilisation, <u>M</u> (<u>SD</u>)				
Community health worker (contact)	0.85 (2.44)	0.79 (1.74)	0.06 (-0.37, 0.50)	0.783
Community-based doctor (contact)	0.63 (1.81)	0.51 (1.39)	0.12 (-0.22, 0.45)	0.491
Psychiatrist (contact)	0.07 (0.53)	0.18 (1.08)	-0.10 (-0.28, 0.07)	0.242
Psychologist (contact)	0.06 (0.60)	0.02 (0.15)	0.04 (-0.05, 0.13)	0.406
Psychiatric Nurse (contact)	0.03 (0.27)	0.00 (0.00)	0.03 (0.00, 0.07)	0.166
Social worker (contact)	0.04 (0.22)	0.00 (0.00)	0.04 (0.00, 0.07)	0.032
Psychiatric inpatient stay (nights)	0.05 (0.33)	0.04 (0.34)	0.02 (-0.05, 0.08)	0.637
Other inpatient stay (nights)	0.16 (0.88)	0.21 (1.20)	-0.05 (-0.27, 0.16)	0.621
Hospital Emergency Department (contact)	0.26 (0.94)	0.16 (0.67)	0.09 (-0.08, 0.26)	0.279
Psychiatric outpatient (contact)	0.00 (0.00)	0.00 (0.00)	0.00	
Other outpatient (contact)	0.35 (2.13)	0.24 (0.96)	0.11 (-0.37, 0.73)	0.518
Day Hospital (Visit)	0.31 (1.66)	0.33 (1.66)	-0.02 (-0.36, 0.32)	0.925
Policlinic (Visit)	0.33 (1.15)	0.30 (1.22)	0.03 (-0.21, 0.27)	0.807
CAM (contact)	0.36 (0.93)	0.65 (5.58)	-0.29 (-1.11, 0.54)	0.493
All community contacts/visits	2.36 (3.72)	2.45 (6.52)	-0.08 (-1.17, 1.00)	0.882
All hospital contacts/visits	1.13 (3.07)	0.98 (2.61)	0.15 (-0.44, 0.73)	0.616
Productivity Loss (days)	4.41 (15.26)	2.65 (10.47)	1.76 (-0.93, 4.44)	0.198

Table T4: Mean Difference in Cumulative Service Utilisation Per Participant at 3-Month Follow-Up

Figure: T1: Cost effectiveness plane – health system perspective Türkiye 3 month follow up



The cost effectiveness plane shows 1,000 bootstrapped randomly sampled pairs of cost and outcomes

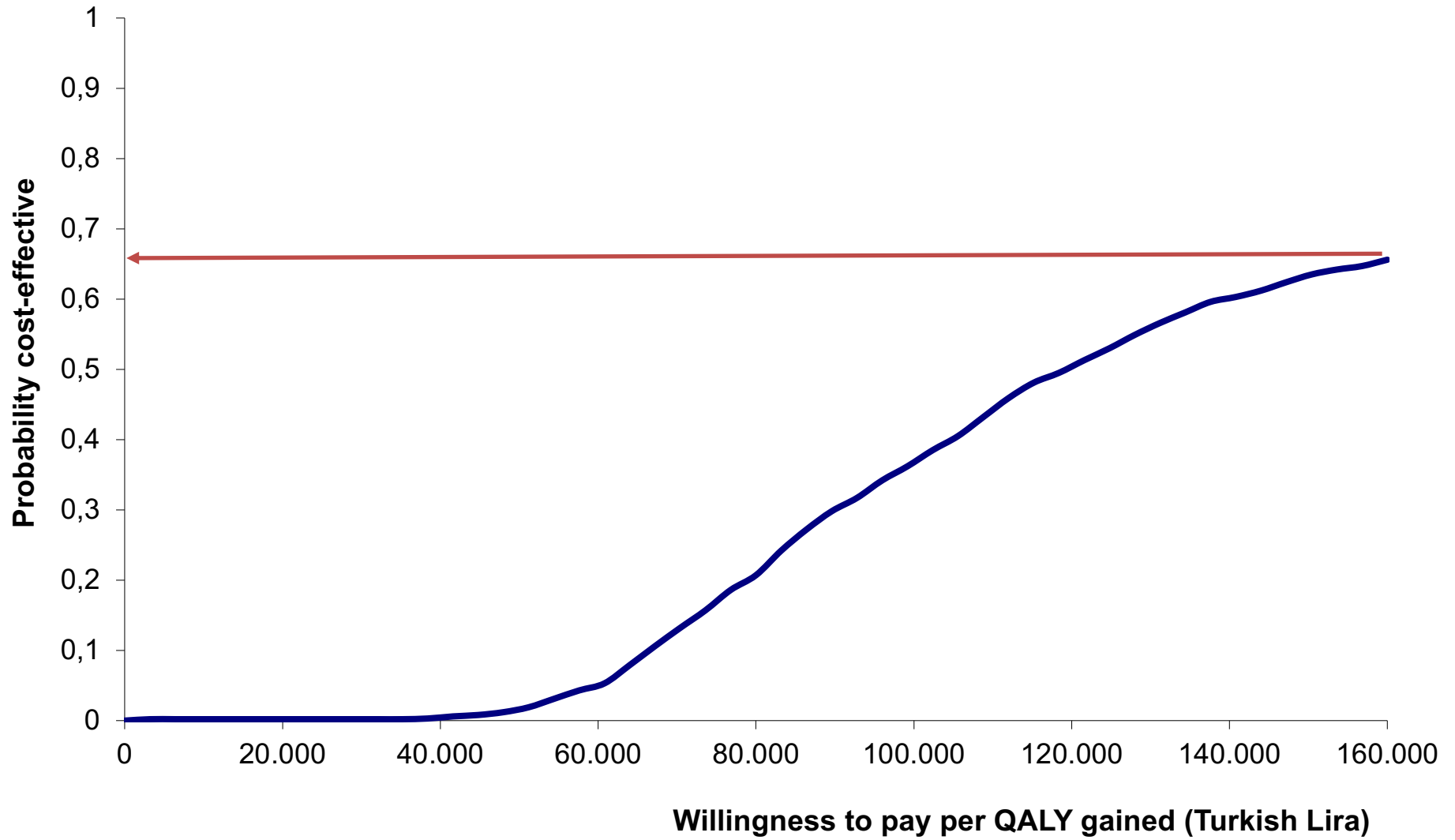


Figure T2: Cost effectiveness acceptability curve. Curve indicates that at a willingness to pay per QALY gained of 160,000 TL there is a 65% chance of gPM+ being cost effective

The results of economic analysis are cautiously positive when looking at quality of life as the primary outcome measure, but the impact on primary outcomes in the effectiveness trial are equivocal. The quality of life gains are small but significant; further analysis will explore whether any of these gains are retained over 12 months, and whether this longer time periods is associated with significant differences in health outcomes. Sub-group analysis may also explore whether there are differences between individuals who attended a higher proportion of gPM+ sessions. Future analysis might also want to look at the use of brief psychological interventions in combination with other interventions including financial and other welfare support measures, as well as any support to obtain employment. These factors have been shown to have an impact on both mental and physical health status (Juárez et al., 2019).

5.4. Switzerland

Pilot study

A pilot RCT was undertaken to designed to test the feasibility and acceptability of individual PM+ among Syrian refugees in Switzerland and to assess the trial procedures in advance of a definite RCT. Full details about the pilot study are reported in Deliverable 5.6 and also in a published paper (Spaaij et al., 2022). A total of N=59 Syrian refugees were randomised into the iPM+ (n=31) or the ETAU arm (n=28). The sample included n=30 female and n=29 male participants. As part of this pilot study, the CSRI designed to collect health service and other resource utilisation data in a Swiss context, was tested. The instrument was well-understood and data were successfully collected on service use. Appropriate unit costs for services were identified (Table CH1)

Table CH1. Unit costs and sources used in Swiss pilot and main trial economic evaluations (values shown in 2019 Swiss Francs)

Type of Cost	Unit cost	Unit	Source
Community health worker (assumed to be equivalent to nurse practitioner)	130	Per hour	Commission des tarifs médicaux LAA (CTM 2020) (Commission des tarifs médicaux LAA (CTM), 2020)
Community-based doctor	158	Per consultation	Report on Swiss health system for the Commonwealth Health Fund (Sturny, 2020)
Psychiatrist	370	Per hour	Rates reported in previous economic evaluation of brief psychological intervention in Switzerland (Park et al., 2018)
Psychologist	256	Per hour	Rates reported in previous economic evaluation of brief psychological intervention in Switzerland (Park et al., 2018)
Social Worker	200	Per consultation	(TARMED Online Browser, 2020) TARMED rates for ambulatory non medical treatment in psychiatry, individual consultation (per 5 minutes) plus estimated overheads
Physiotherapist	125	Per session	(Confederation suisse, 2018) Commission de Tarifs Médicaux. Ambulatory physiotherapist (Tariff Code 7301 Forfait par séance pour la physiothérapie Générale) plus Tariff code 7401 supplement for potential combination of general therapies, plus estimated overheads
Crisis service psychiatry	370	Per consultation	Assumed same as psychiatrist consultation (Park et al., 2018)
Hospital Psychiatric Inpatient Stay	700	Per day	Federal Office of Statistics 2020(Office fédéral de la statistique, 2020)
Hospital Inpatient Stays - General health	500	Per day	Basel University Hospital Charge Per Night (Universitätsspitals Basel, 2020)
Hospital Outpatient Psychiatric Services	370	Per hour	Rates reported in previous economic evaluation of brief psychological intervention in Switzerland (Park et al., 2018)
Hospital Outpatient Services	245	Per visit	Report on Swiss health system for the Commonwealth Health Fund (Sturny, 2020)
Hospital A&E	427	Per visit	(news@thelocal.ch, 2019) Average cost reported to

			Parliament by Thomas Weibel (December 2019)
Minimum Wage Rate	20	Per hour	(Commission Tripartite, 2019, Service de l'économie et de l'emploi, 2020) There is no national minimum wage rate in Switzerland; only a minority of cantons have these minimum wages. We have used reported minimum wage rates that are used in cantons of Jura and Neuchatel these were the first cantons to enforce minimum wage regulations. The Neuchatel rate was raised to 20.08 CHF in 2020.
Complementary Medicine Consultation	50	Per consultation	Our own estimation based on average of consultation costs for CAM reported in collected CSRI pilot data

The pilot study revealed very low use of health services in both groups, with no significant differences in service use at each time point for all categories (Table CH2). There was very little contact with psychiatric inpatient or outpatient services in either group. At 3 month follow up mean service contacts were greatest for community doctors and physiotherapists. Even though most respondents were eligible to work there was little reported impact on productivity. Moreover, as shown in Table CH3 given the small sample size there was no significant difference in the cost of health services used or in productivity losses, although these were higher in the PM+ group.

**Table CH2. Health service utilisation between PM+ and Enhanced Care as Usual Groups – Pilot Study
(Mean (SD) at baseline, post-assessment and 3-month follow up (complete cases only))**

Service	Baseline		Post-assessment		3 MFU	
	PM+ (n=30)	ECAU (n=28)	PM+ (n=23)	ECAU n=20)	PM+ (n=21)	ECAU (n=19)
Community health worker (contact)	0.03 (0.18)	0.36 (1.34)	0.04 (0.21)	0.10 (0.45)	0.00	0.00
Community-based doctor (contact)	0.70 (0.99)	1.93 (4.82)	1.00 (1.60)	0.80 (1.40)	1.95 (2.67)	1.63 (2.69)
Psychiatrist (contact)	1.00 (2.46)	0.71 (2.40)	0.83 (2.68)	0.65 (2.68)	0.86 (2.03)	0.00
Psychologist (contact)	0.40 (2.19)	0.21 (1.13)	0.52 (1.73)	0.00	0.57 (2.62)	0.63 (2.75)
Social worker (contact)	0.20 (0.66)	0.18 (0.55)	0.43 (1.16)	0.05 (0.22)	0.14 (0.48)	0.21 (0.71)
Physiotherapist (contact)	0.70 (2.53)	0.86 (2.43)	2.87 (10.81)	1.75 (6.05)	2.10 (5.57)	1.27 (5.51)
Crisis service psychiatry (contact)	0.00	0.00	0.22 (1.04)	0.00	0.00	0.00
Psychiatric inpatient stay (nights)	0.00	0.68 (2.37)	0.00	0.00	0.00	0.00
Other inpatient stay (nights)	0.03 (0.18)	0.21 (0.96)	0.09 (0.29)	0.00	0.71 (1.90)	0.53 (2.29)
Psychiatric outpatient (contact)	0.20 (0.76)	0.04 (0.19)	0.00	0.00	0.00	0.00
Hospital Emergency Department (contact)	0.07 (0.25)	0.54 (1.50)	0.00	0.00	0.10 (0.30)	0.11 (0.32)
Other outpatient (contact)	0.07 (0.25)	0.07 (0.38)	0.13 (0.46)	0.00	0.19 (0.87)	0.00
Medicine (doses)	18.2 (44.6)	22.75 (63.75)	15.83 (59.18)	0.00	21.67 (39.72)	9.58 (28.70)
CAM (contact)	0.37 (1.83)	0.89 (3.97)	0.00	0.10 (0.31)	0.00	1.11 (4.58)
Productivity Loss (days)	0.83 (4.56)	1.5 (6.62)	2.17 (9.39)	0.00	0.14 (0.47)	0.42 (1.84)

Table CH3: Mean differences in health and productivity costs (2019 CHF) at 3 month follow up (complete cases only).

Type of Cost	PM+	ECAU	Mean Difference (BCa 95% CI)	p
Health Service Utilisation, <u>M</u>				
Community health worker	1.30	5.43	-4.12 (-7.35, 15.60)	0.467
Community-based doctor	404.48	309.42	95.06 (-166.08, 396.28)	0.531
Psychiatrist	547.60	200.42	347.18 (-251.51, 909.63)	0.266
Psychologist	245.76	128.00	117.76 (-294.93, 602.10)	0.612
Social Worker	63.80	29.14	34.67 (-40.77, 113.69)	0.409
Physiotherapist	550.00	307.29	242.71 (-524.56, 1341.49)	0.564
Crisis Psychiatry	74.00	0.00	74.00 (-78.73, 226.73)	0.105
Hospital Non-Psychiatric Inpatient Stays	340.00	208.33	131.67 (-421.18, 626.67)	0.631
Hospital Emergency Services	34.16	35.58	-1.42 (-67.36, 66.08)	0.967
Hospital Non-Psychiatric Outpatient Services	68.60	0.00	68.60 (-21.48, 158.68)	0.129
Complementary Medicine	0.00	47.92	-47.92 (-133.38, 38.01)	0.399
Total Community Health Services Costs	1886.94	1027.60	859.34 (-650.47, 2355.01)	0.302
Total Hospital Costs, <u>M</u>	442.76	243.92	198.84 (-410.82, 764.60)	0.564
Productivity losses, <u>M</u>	296.80	46.67	250.13 (-96.32, 849.14)	0.338
Total Health and Productivity Costs, <u>M</u>	2626.50	1318.19	1308.32 (-496.13, 3133.73)	0.168

Economic analysis alongside main trial

As noted in Deliverable D5.6, the results of the definitive RCT are of a preliminary nature, with 12 month follow up ongoing at the time of writing. The economic analysis discussed here only covers data to 3 month follow up. We only provide some limited information on these findings in this version of the report; a more extensive version of the report with these findings will be available from the authors once the results have been accepted for publication.

The study enrolled 54 participants, PM+ (n=25) and ECAU (n=29). This is lower than planned for, so the study is underpowered. The trial reported that there was a significant reduction in mean WHODAS scores in both the PM+ and ECAU groups between baseline and 3-month follow-up in the ECAU group (mean difference = 6.5, SE = 1.4, p < .001), as well as in the PM+ group (mean difference = 4.6, SE = 1.5, p = .003). In the economic analysis we were interested in the marginal differences in quality of life between baseline and 3 months between the two groups.

We transformed the WHODAS 2.0 12 item scores into utility weights that can be used to estimate QALYs. Utility weights of 1 represent perfect quality of health and 0 the worst quality of health. At baseline mean utility weights for the PM+ and ECAU groups were 0.7556 (SD 0.07953, 95% CI 0.7278 – 0.7831) and 0.7735 (SD 0.06589, 95% CI 0.7462 – 0.8010) respectively. This difference was not significant. Table CH4 shows that there were QALY gains in both groups between baseline and 3 month follow up. There was no significant difference in quality of life enjoyed between the two groups at 3 month follow up, although quality of life gains were greater in the ECAU group.

Table CH 4: Changes in quality of life between baseline and 3 month follow up.

	QALYs gained between baseline and post-assessment		QALYs gained between post-assessment and 3 month follow up		Total QALYs gained	
	PM+ (n=29)	ECAU (n=25)	PM+ (n=29)	ECAU (n=25)	PM+ (n=29)	ECAU (n=25)
Mean	0.0881	0.0915	0.1958	0.2013	0.2839	0.2928
95% CI	(0.00674-0.00871)	(0.0889-0.0943)	(0.1899-0.2016)	(0.1948-0.2077)	(0.2751-0.2920)	(0.2837-0.3017)
Std Dev	0.0079	0.0068	0.0160	0.0161	0.0230	0.0222
Mean difference	0.00347		0.00541		0.00887	
95% CI for difference	(-0.00054, 0.00748)		(-0.00337, 0.01418)		(-0.00348, 0.02122)	
Significance	p=0.89		p=0.222		p=0.155	

Table CH5 indicates that there were no significant differences in any element of health service utilisation between the two groups at 3 month follow up. Physiotherapists, as seen in the pilot study, were the most used health service between baseline and follow up in both groups; the next most utilised service was primary care doctors. There were very few hospital inpatient stays. Table CH6 reports the mean difference in total health service utilisation and productivity costs between the two groups between baseline and 3 month follow up. While costs were lower in the PM+ group this difference was not significant, and there were no significant differences between any element of cost.

In summary we did not find any significant difference in the primary outcome used in the economic analysis. The effectiveness analysis for other outcome measures (reported separately) also was unable to come to any definitive conclusions. We also did not observe any significant difference in impacts on health systems and productivity losses. With no impact on outcomes or costs we have not synthesised cost and outcome data to generate incremental cost per QALY results. The lack of any definitive conclusion is likely to be due in part to the trial being underpowered as a result of challenges in recruitment during the COVID-19 crisis, as well as changes to Swiss immigration policy which reduced the number of new Syrian migrants entering Switzerland. and the effectiveness results. We are awaiting longer term cost and outcomes data at 12 months follow up,

and will explore what impact this might have. We potentially might also consider pooling data across the pilot and main trials to increase the number of observations used in the economic analysis.

**Table CH5. Health service utilisation between PM+ and Enhanced Care as Usual Groups – Main Study
(Mean (SD) at baseline, post-assessment and 3-month follow up)**

Service	Baseline		Post-assessment		3 MFU	
	PM+ (n=29)	ECAU (n=25)	PM+ (n=29)	ECAU (n=25)	PM+ (n=29)	ECAU (n=25)
Community health worker (contact)	0.28 (1.00)	0.00 (0.00)	0.00 (0.00)	0.36 (1.32)	0.00 (0.00)	0.00 (0.00)
Community-based doctor (contact)	2.73 (3.99)	1.48 (1.45)	0.93 (1.87)	0.80 (1.22)	1.10 (1.57)	0.92 (1.58)
Psychiatrist (contact)	0.38 (1.18)	0.84 (1.65)	0.69 (2.62)	1.12 (3.33)	0.90 (2.30)	1.20 (3.25)
Psychologist (contact)	0.17 (0.93)	0.32 (1.60)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Psychiatric Nurse (contact)	0.35 (0.19)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.07 (0.37)	0.00 (0.00)
Social worker (contact)	0.28 (0.84)	0.00 (0.00)	0.10 (0.41)	0.48 (2.40)	0.00 (0.00)	0.48 (2.40)
Physiotherapist (contact)	1.41 (3.49)	1.28 (6.00)	1.10 (3.27)	2.40 (6.06)	0.90 (3.76)	1.56 (4.97)
Home care (contact)	0.41 (2.23)	0.00 (0.00)	0.21 (1.11)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Alcohol/Drug Consultation	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Crisis service psychiatry (contact)	0.00 (0.00)	0.00 (0.00)	0.04 (0.20)	0.00 (0.00)	0.00 (0.00)	0.04 (0.20)
Other	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Psychiatric inpatient stay (nights)	0.69 (2.54)	0.00 (0.00)	0.24 (1.30)	0.00 (0.00)	0.26 (1.41)	0.00 (0.00)
Other inpatient stay (nights)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Psychiatric outpatient (contact)	0.14 (0.74)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Hospital Emergency Department (contact)	0.17 (0.60)	0.16 (0.62)	0.03 (0.19)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Other outpatient	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.08 (0.40)	0.00 (0.00)	0.08 (0.40)
CAM (contact)	0.28 (1.31)	0.00 (0.00)	0.03 (0.19)	0.00 (0.00)	0.03 (0.19)	0.00 (0.00)
Productivity Loss (days)	1.71 (5.20)	1.2 (6.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)

No statistically significant differences unless indicated.

Table CH6: Main trial mean differences in health and productivity costs (2019 CHF) at 3 month follow up

Type of Cost	PM+ (29)	ECAU (25)	Mean Difference (BCa 95% CI)	p
Health Service Cost, <u>M (SD)</u>				
Community health worker	0.00 (0.00)	11.71 (42.93)	-11.71 (-29.44, 6.00)	0.185
Community-based doctor	321.44 (509.32)	271.76 (348.91)	49.69 (-192.69, 292.06)	0.674
Psychiatrist	585.49 (1,453.12)	858.40 (2,406.71)	-272.91 (-1,389.79, 843.98)	0.624
Psychologist	0.00 (0.00)	0.00 (0.00)		
Psychiatric Nurse	0.07 (0.37)	0.00 (0.00)	0.07 (-0.08, 0.22)	0.326
Social Worker	20.67 (81.77)	156.64 (783.21)	-135.97 (-460.47, 188.52)	0.396
Physiotherapist	249.27 (842.78)	495.00 (1314.72)	-245.73 (-864.29, 372.83)	0.427
Home Care	0.21 (1.11)	0.00 (0.00)	0.21 (-0.22, 0.63)	0.326
Crisis Psychiatry	0.00 (0.00)	29.60 (102.45)	-29.60 (-71.89, 12.69)	0.161
Hospital Psychiatric Inpatient Stays	352.41 (1,318.97)	0.00 (0.00)	352.41 (-149.29, 854.12)	0.161
Hospital Non-Psychiatric Inpatient Stays	0.00 (0.00)	0.00 (0.00)		
Hospital Emergency Services	14.72 (79.29)	0.00 (0.00)	14.72 (-15.44, 44.89)	0.326
Hospital Non-Psychiatric Outpatient Services	0.00 (0.00)	39.20 (135.67)	-39.20 (-95.20, 16.80)	0.161
Complementary Medicine	3.45 (12.89)	0.00 (0.00)	3.45 (-1.73, 8.63)	0.161
Total Community Health Services Costs	1,180.60 (2417.76)	1,823.12 (3,716.14)	-642.52 (-2,397.25, 1112.22)	0.464
Total Hospital Costs	367.13 (1317.27)	39.20 (135.67)	327.94 (-175.66, 831.53)	0.193
Total Health Care Costs	1,547.74 (3,079.17)	1,862.32 (3,709.48)	-314.58 (-2,199.11, 1,569.95)	0.738
Productivity losses	0.00 (0.00)	0.00 (0.00)		
Total Health and Productivity Costs	1,547.74 (3,079.17)	1,862.32 (3,709.48)	-314.58 (-2,199.11, 1,569.95)	0.738

6. Results SbS studies

6.1. Egypt

There were 538 individuals randomised between SbS (266) and CAU (272) in the Egyptian study. The effectiveness trial indicated that there was a small but significant impact on psychological distress in the SbS group. Full details on the trial and characteristics of participants are available in Deliverable D6.3.

In summarising the results of the economic analysis conducted alongside the trial, we only provide some limited information on findings in this version of the report; a more extensive version of the report with these findings will be available from the authors once the results have been accepted for publication. In short, the results of our cost effectiveness analysis at 3 month follow up is inconclusive. In short, there is a very small positive but non-significant QALY gain, while there is no impact on resource use and costs.

The effectiveness trial indicated that there was a small but significant improvement in functioning as measured by the WHODAS 2.0 12 in the SbS. To assess the primary outcome in the economic analysis we transformed WHODAS 2.0 domain scores in order to generate utility weights in order to calculate QALYs. There was a very small but insignificant QALY gain in the SbS group compared with CAU (0.001) ($p=0.509$). Quality of life increased in the SbS group in both periods: baseline to post-intervention follow up as well as from post-intervention to three month follow up. In contrast quality of life declined marginally in the CAU group in the period from post-intervention to three month follow up. If the QALY gains in the SbS group are sustained over a longer time period then the economic case for investment may be strengthened further.

Having adapted the CSRI for use as part of a wider collection of data online through mobile phone apps we also looked at the impacts of intervention on resource use and service costs. There were no significant impacts on resource use and costs. As Table E1 indicates mean reported use of service is very limited, although a minority of individuals used a range of services, including complementary medicine. There was almost no use of psychiatric inpatient services in either group. Table E1 indicates that there was no significant difference in any type of service utilisation. Daily use of sleep medications was of borderline significance, when using bias corrected and accelerated bootstrapping, to account for skewness in service use the lower use in the SBS group had a p value of 0.087. A limitation of the CSRI for the SBS analysis, is that we do not know about changes in the use of secondary care services, such as hospital stays for non-mental health related issues.

Exploratory analysis in the effectiveness analysis (see D6.3) suggests that using a subset of individuals who per-protocol completed all sessions of SbS had more improved outcomes. This is something that can also be

explored in economic analysis, as well as looking at differences in participant characteristics including differences in specific health care service utilisation at baseline.

Table E1: Mean Difference in Cumulative Service Utilisation Per Participant at 3-Month Follow-Up

Type of Contact	SBS N=266	CAU N=272	Mean Difference (BCa 95% CI)	<u>P</u>
Service Utilisation/Time out of Role, <u>M</u> (<u>SD</u>)				
Community health worker (Minutes)	1.68 (4.01)	1.69 (5.70)	-0.15 (-0.95, 0.75)	0.971
Community-based doctor (Minutes)	2.21 (5.11)	1.83 (4.79)	0.37 (-0.55, 1.18)	0.389
Psychiatrist (Minutes)	0.46 (2.88)	0.18 (1.01)	0.29 (-0.03, 0.66)	0.170
Psychologist (Minutes)	0.57 (3.12)	0.13 (1.21)	0.44 (0.09, 0.85)	0.087
Psychiatric Nurse (Minutes)	0.27 (2.44)	0.04 (0.44)	0.22 (-0.02, 0.54)	0.199
Social worker (Minutes)	0.53 (1.78)	0.44 (1.37)	0.10 (-0.17, 0.39)	0.532
Physio (Minutes)	0.72 (3.24)	0.83 (4.62)	-0.12 (-0.82, 0.54)	0.713
Home Care (Minutes)	1.27 (5.03)	0.85 (2.94)	0.41 (-0.21, 1.15)	0.265
Self-Help (Minutes)	0.09 (0.64)	0.13 (1.06)	-0.03 (-0.22, 0.13)	0.687
Alcohol/Drug Consultation Centres	0.01 (0.11)	0.00 (0.06)	0.01 (-0.01, 0.02)	0.309
Crisis Psychiatry Service	0.18 (1.03)	0.18 (0.99)	0.01 (-0.15, 0.16)	0.919
Psychiatric inpatient stay (Days)	0.06 (0.92)	0.01 (0.18)	0.05 (-0.03, 0.21)	0.452
Psychiatric outpatient (visits)	0.09 (0.98)	0.01 (0.15)	0.07 (-0.01, 0.22)	0.355
Mood meds (days of use)	1.96 (12.63)	0.64 (3.88)	1.32 (-0.10, 3.24)	0.154
Anxiety meds (days of use)	1.80 (8.45)	1.48 (9.02)	0.32 (-1.36, 1.85)	0.706
Sleep meds (days of use)	2.64 (10.98)	1.92 (9.73)	0.72 (-1.10, 2.66)	0.435
CAM (Minutes)	2.54 (10.98)	3.80 (18.22)	-1.25 (-3.97, 1.25)	0.345
All community (Minutes)	10.54 (22.11)	10.11 (23.98)	0.43 (-3.61, 4.40)	0.820
All Meds (days of use)	6.40 (28.38)	4.03 (20.98)	2.36 (-1.89, 6.96)	0.314
Productivity Loss (days)	16.63 (27.95)	15.65 (28.29)	0.97 (-3.88, 5.48)	0.675

6.2. Germany

There were 633 individuals randomised between SbS (337) and CAU (295) in the German study. Full details on the trial and characteristics of participants are available in Deliverable D6.3. There were no significant impacts on any effectiveness outcomes in the trial. In summarising the results of the economic analysis here, we only provide some limited information on findings in this version of the report; a more extensive version of the report with these findings will be available from the authors once the results have been accepted for publication. In short, the results of our cost effectiveness analysis at 3 month follow up do not suggest that the intervention is cost effective in the short term, with no impact on quality of life, and also no impact on resource use and costs.

The effectiveness trial indicated that there was no significant improvement in functioning as measured by the WHODAS 2.0 12 in the SbS. To assess the primary outcome in the economic analysis we transformed WHODAS 2.0 domain scores in order to generate utility weights in order to calculate QALYs. There was virtually no difference between QALY changes in the two groups and this difference was not significant (-0.003) ($p=0.154$). QALY gains were greater for both groups in the periods to post-intervention follow up as well as three month follow up.

Having adapted the CSRI for use as part of a wider collection of data online through mobile phone apps we also looked at the impacts of intervention on resource use and service costs. As Table G1 indicates mean reported use of service is very limited, although a minority of individuals used a range of services, including complementary medicine. There was almost no use of psychiatric inpatient services in either group. Table G1 indicates that there is a significant lower amount of time spent with psychologists ($p=0.016$) and social workers ($p=0.042$) in the SBS groups. No other significant differences in resource utilisation were seen. These findings must be interpreted cautiously, a limitation of the CSRI for the SBS analysis, is that we do not know about changes in the use of secondary care services, such as hospital stays for non-mental health related issues.

It is unclear if SbS may be cost effective over the longer term, this will need to be determined when 12 month follow up data become available. Exploratory analysis in the effectiveness analysis suggests that using a subset of individuals who per-protocol completed all sessions of SbS had more improved outcomes. This is something that can also be explored, as well as looking at differences in participant characteristics including differences in specific health care service utilisation at baseline.

Table G1: Mean Difference in Cumulative Service Utilisation Per Participant at 3-Month Follow-Up

Type of Contact	SBS N=337	CAU N=296	Mean Difference (BCa 95% CI)	P
Service Utilisation/Time out of Role, <u>M</u> (<u>SD</u>)				
Community health worker (Minutes)	0.74 (3.32)	0.84 (2.92)	-0.11 (-0.59, 0.41)	0.661
Community-based doctor (Minutes)	1.01 (4.41)	1.01 (2.31)	-0.01 (-0.52, 0.57)	0.980
Psychiatrist (Minutes)	0.08 (0.46)	0.34 (2.46)	-0.26 (-0.54, 0.03)	0.156
Psychologist (Minutes)	0.07 (0.48)	0.40 (1.79)	-0.32 (-0.55, -0.13)	0.016
Psychiatric Nurse (Minutes)	0.02 (0.27)	0.04 (0.58)	-0.02 (-0.10, 0.04)	0.708
Social worker (Minutes)	0.11 (0.80)	0.32 (1.52)	-0.21 (-0.41, -0.04)	0.042
Physio (Minutes)	0.20 (1.36)	0.22 (1.62)	-0.02 (-0.26, 0.21)	0.878
Home Care (Minutes)	0.48 (6.42)	0.04 (0.36)	0.44 (-0.02, 1.16)	0.379
Self-Help (Minutes)	0.00 (0.00)	0.00 (0.06)	0.00 (-0.01, 0.00)	0.154
Alcohol/Drug Consultation Centres	0.00 (0.00)	0.00 (0.00)		
Crisis Psychiatry Service	0.00 (0.05)	0.01 (0.12)	-0.01 (-0.03, 0.00)	0.141
Psychiatric inpatient stay (Days)	0.00 (0.00)	0.03 (0.58)	-0.03 (-0.10, 0.03)	0.154
Psychiatric outpatient (visits)	0.10 (1.40)	0.02 (0.17)	0.09 (-0.01, 0.24)	0.258
Mood meds (days of use)	1.67 (11.04)	3.01 (15.10)	-1.34 (-3.59, 0.64)	0.209
Anxiety meds (days of use)	1.51 (10.66)	1.72 (9.76)	-0.21 (-1.83, 1.39)	0.791
Sleep meds (days of use)	1.19 (9.72)	1.97 (15.02)	-0.78 (-3.01, 1.06)	0.459
CAM (Minutes)	1.38 (9.86)	2.61 (17.50)	-1.23 (-3.94, 0.98)	0.303
All community (Minutes)	4.09 (17.20)	5.84 (20.35)	-1.75 (-4.72, 1.11)	0.251
All Meds (days of use)	4.37 (28.40)	6.69 (32.54)	-2.33 (-7.27, 2.48)	0.356
Productivity Loss (days)	4.62 (16.33)	4.18 (14.37)	0.45 (-1.87, 2.87)	0.706

6.3. Sweden

There were 184 individuals randomised between SbS (95) and CAU (89) in the Swedish study. Full details on the trial and characteristics of participants are available in Deliverable D6.3. That trial indicated greater improvements in psychological distress by 3 month follow up in the SbS group, but this was not statistically significant. There were no significant impacts on other outcomes measures in the effectiveness analysis.

In summarising the results of the economic analysis here, we only provide some limited information on findings in this version of the report; a more extensive version of the report with these findings will be available from the authors once the results have been accepted for publication. In short, the results of our cost effectiveness analysis at 3 month follow up indicate inconclusive results, with a small but not significant positive impact on quality of life. There was also no impact on resource use and costs. It is unclear if SbS will be cost effective; all other things being equal, the case will be strengthened if any quality of life gains can be sustained beyond 3 months.

The effectiveness trial indicated that there was greater improvement in functioning as measured by the WHODAS 2.0 12 in the SbS but this was not significant. To assess the primary outcome in the economic analysis we transformed WHODAS 2.0 domain scores in order to generate utility weights in order to calculate QALYs. QALY gains were marginally greater by 0.01 QALYs in the SbS group, but again this difference was not significant ($p=0.263$). QALY gains were greater for both the period from baseline to post-intervention follow up, as well as from post-intervention to three month follow up.

Having adapted the CSRI for use as part of a wider collection of data online through mobile phone apps we also looked at the impacts of intervention on resource use and service costs. We did not identify any overall significant change in resource utilisation or in costs. As Table S1 indicates mean reported use of service is very limited, although a minority of individuals used a range of services, including complementary medicine. There was no use of psychiatric inpatient services in either group. Table S1 indicates the only significant difference in service utilisation is for time spent with community health workers, which is significantly less in the SBS group (0.48 vs 1.15 minutes) $p=0.044$. Daily use of sleep medications was of borderline significance, when using bias corrected and accelerated bootstrapping, to account for skewness is service use the lower use in the SBS group had a p value of 0.065. A limitation of the CSRI for the SBS analysis, is that we do not know about changes in the use of secondary care services, such as hospital stays for non-mental health related issues.

Table S1: Mean Difference in Cumulative Service Utilisation Per Participant at 3-Month Follow-Up

Type of Contact	SBS N=95	CAU N=89	Mean Difference (BCa 95% CI)	P
Service Utilisation/Time out of Role, <u>M</u> (<u>SD</u>)				
Community health worker (Minutes)	0.48 (1.57)	1.15 (2.69)	-0.67 (-1.35, -0.06)	0.044
Community-based doctor (Minutes)	0.37 (1.18)	0.67 (1.62)	-0.31 (-0.70, 0.71)	0.142
Psychiatrist (Minutes)	0.14 (1.23)	0.17 (0.83)	-0.03 (-0.30, 0.31)	0.837
Psychologist (Minutes)	0.16 (1.25)	0.20 (0.84)	-0.04 (-0.28, 0.25)	0.777
Psychiatric Nurse (Minutes)	0.02 (0.21)	0.06 (0.38)	-0.04 (-0.13, 0.05)	0.403
Social worker (Minutes)	0.11 (0.59)	0.11 (0.51)	-0.01 (-0.16, 0.15)	0.441
Physio (Minutes)	0.12 (0.78)	0.84 (4.27)	-0.73 (-1.92, 0.02)	0.241
Home Care (Minutes)	0.16 (1.14)	0.00 (0.00)	0.16 (-0.05, 0.50)	0.180
Self-Help (Minutes)	0.00 (0.00)	0.00 (0.00)		
Alcohol/Drug Consultation Centres	0.00 (0.00)	0.00 (0.00)		
Crisis Psychiatry Service	0.02 (0.21)	0.01 (0.11)	0.01 (-0.03, 0.06)	0.681
Psychiatric inpatient stay (Days)	0.00 (0.00)	0.00 (0.00)		
Psychiatric outpatient (visits)	0.00 (0.00)	0.02 (0.21)	-0.02 (-0.07, 0.02)	0.320
Mood meds (days of use)	1.05 (9.28)	0.81 (4.97)	0.24 (-1.28, 2.39)	0.823
Anxiety meds (days of use)	1.05 (9.28)	0.83 (4.98)	0.22 (-1.30, 2.37)	0.839
Sleep meds (days of use)	0.31 (1.88)	2.35 (7.74)	-2.04 (-4.14, -0.46)	0.065
CAM (Minutes)	3.46 (21.22)	5.09 (23.78)	-1.63 (-8.04, 4.83)	0.647
All community (Minutes)	5.03 (21.62)	8.31 (25.66)	-3.28 (-10.23, 3.60)	0.383
All Meds (days of use)	2.41 (18.79)	3.99 (15.56)	-1.58 (-6.44, 3.52)	0.587
Productivity Loss (days)	4.27 (16.58)	4.72 (17.53)	-0.45 (-5.41, .406)	0.864

7. EASE study: economic analysis

There were 198 adolescents randomised between EASE (80) and ECAU (118) in the Lebanese study. No definitive conclusions could be drawn, there were some positive impacts at 3 months but these dissipated at 12 months when the intervention did not appear to be any more effective than ECAU. However, this trial was ended earlier because of the extraordinary conflation of challenging circumstances in Lebanon during the study, including the economic crisis in the country, the explosion in the port of Beirut, political instability and violent demonstrations. Full details on the trial, characteristics of participants and outcomes are available in Deliverable D4.5.

The trial in Lebanon was not concerned with PM+ or SbS and moreover did not collect data on an outcome measure that can be used to generate the primary outcome measure in an economic analysis, the quality adjusted life year (QALY). That said, the trial provides an opportunity to determine whether there any change in health service utilisation and other impacts such as time out of role for both adolescents and their guardians is associated with any positive effects of the EASE intervention. Therefore, we worked iteratively with the effectiveness trial team to design a CSRI to collect data from the parents/guardians of adolescents on resource use and costs to allow a cost and consequence analysis to be performed. The CSRI was field tested in Lebanon and appeared to work well. The CSRI here collects information on impacts both on adolescents and on children, including any potential use of health services in Syrian as well as Lebanon.

As we have noted the results of the trial are inconclusive because of the small sample size, and in fact the effectiveness study may even suggest that there might be a case for greater investment in the ECAU intervention. The CSRI data for the economic analysis are also slightly smaller, as because the trial was halted not all participants for whom CSRI data were collected were then allocated to an arm of the trial. Therefore, we do not report findings here, but a more extensive version of this report with findings on impact on resource utilisation relative to the costs of EASE and ECAU groups at 3 and 12 month follow up periods will be available from the authors once the results have been accepted for publication. The analysis also reveals frequent out of pocket payments made to make use of health services. The data are also being used to inform modelling work on the potential cost consequences of scaling up interventions, where we also look at the level of effect needed in order for the intervention to be considered cost effective in a Lebanese context. (See Deliverable D7.3).

8. Conclusions

This report summarised economic evaluations undertaken alongside 7 implementation trials, four for PM+ in Jordan, Netherlands, Switzerland, and Türkiye, and three trials of SbS in Egypt, Germany and Sweden. In the economic analysis the primary outcome measure used is the Quality Adjusted Life Year, allowing investments in interventions to improve refugee mental health to be compared with any other health-related intervention. To our knowledge these are the first economic evaluations to capture cost per QALY gained for these brief psychological interventions; one previous economic evaluation of PM+ in Pakistan relied on specific health impacts alone (Hamdani et al., 2020) which can make it more difficult for funders to make choices between many different health related interventions. Our economic analysis alongside the pilot study in the Netherlands also focused on cost per recovery gained because of the small sample size (de Graaff et al., 2020). The evidence base more generally is limited, one study which had QALYs as the main health economic outcome for a self-help intervention for refugees in Türkiye has been shown to be cost effective (Park et al., 2022), while two studies in Germany for collaborative care and online self-help app have not been shown to be cost effective (Böge et al., 2022, Rohr et al., 2021).

The results of our analyses are also mixed and very context-dependent. Three of the four PM+ trials, Jordan, Netherlands and Türkiye, suggest that there is a potential economic case for investment with small but significant improvements in quality of life at 3-month follow up. However, only in Türkiye is the cost per QALY gained likely to be considered cost effective. In Jordan and the Netherlands, the cost per QALY gained will become more attractive if some of the costs associated with implementation, such as training and supervision can be reduced. This seems very feasible, if interventions are sustained. It is difficult to draw conclusions on the Swiss trial because the sample size is small and unlikely to be able to detect significant impacts on either costs or quality of life. In the case of all PM+ studies, 12-month follow up analysis will provide information on longer term impacts: if quality of life gains can be sustained for some time beyond three months, even if the effect dissipates over time, and/or if there is a favourable change in the use of health services and time out of everyday activities, then the economic case will be strengthened.

In respect of the SBS studies, the results are inconclusive. In all countries there was no significant difference in health service utilisation. In Egypt and Sweden there are small positive improvements in quality of life but these were not significant at 3-month follow up. The nature of online interventions means that the rates of intervention completion usually are lower than those seen in face-to-face trials; exploratory analysis

undertaken as part of the effectiveness trial suggests that there may be more impacts for individuals who fully completed treatment. We may also see more impacts on cost effectiveness in sub-group analysis, as well as when 12-month follow data are analysed.

More generally, future research may wish to look at the combinations of interventions rather than interventions alone, something that was noted in the EASE trial as a potential future research possibility given the potential therapeutic benefit that enhanced care as usual may have had in Lebanon. Another area for future work may be to look at ways in which to assess the cost effectiveness of booster sessions to reinforce any benefits to mental health and quality of life gained.

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10. Research outputs

Published

Acarturk, C., E. Uygun, Z. Ilkkursun, T. Yurtbakan, G. Kurt, J. Adam-Troian, I. Senay, R. Bryant, P. Cuijpers, N. Kiselev, D. McDaid, N. Morina, Z. Nisanci, A. L. Park, M. Sijbrandij, P. Ventevogel, and D. C. Fuhr. 2022. 'Group problem management plus (PM+) to decrease psychological distress among Syrian refugees in Türkiye: a pilot randomised controlled trial', *BMC Psychiatry*, 22: 8.

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Feasibility and acceptability of Problem Management Plus (PM+) among Syrian refugees and asylum seekers in Switzerland: a mixed-method pilot randomized controlled trial

In preparation

Cost-effectiveness of group PM+ for Syrian refugees in Jordan at 3-month follow up (Lead author LSE)

Economic impacts and cost-effectiveness of group PM+ for Syrian refugees in Jordan at 12-month follow up (Lead author LSE)

Cost-effectiveness of group PM+ for Syrian refugees in Türkiye at 3-month follow up (Lead author LSE)

Economic impacts and cost-effectiveness of group PM+ for Syrian refugees in Türkiye at 12-month follow up (Lead author LSE)

Cost-effectiveness of individual PM+ at 3-month follow up for Syrian refugees in Netherlands (Lead author LSE)

Economic impacts and cost-effectiveness of individual PM+ at 12-month follow up for Syrian refugees in Netherlands (Lead author LSE)

Cost-effectiveness of individual PM+ at 3-month and 12 month follow ups for Syrian refugees in Switzerland (Lead author LSE)

Cost-effectiveness of SbS for Syrian refugees in Egypt at 3-month follow up (Lead author LSE)

Cost-effectiveness of SbS for Syrian refugees in Germany at 3-month follow up (Lead author LSE)

Cost-effectiveness of SbS for Syrian refugees in Sweden at 3-month follow up (Lead author LSE)

Implementation costs and economic impact of EASE in Lebanon (Lead author LSE)