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A qualitative study on the impacts of COVID-19 on the delivery of randomised controlled trials evaluating lay-delivered psychological interventions in five countries

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ABSTRACT

COVID-19 is having substantial impacts on research conduct, including clinical trials. However, there is limited research investigating the impact of the pandemic on the conduct of clinical trials and barriers to the delivery of interventions. The current study contributes to filling this gap by investigating the impacts of COVID-19 and related mitigation strategies in the context of five randomised controlled trials (RCTs) of lay-delivered psychological interventions for Syrian refugees in Jordan, Lebanon, the Netherlands, Switzerland, and Turkey. We conducted semi-structured interviews with purposively selected researchers ($N = 14$) across all five countries. Data were analysed using codebook thematic analysis. The trial researchers highlighted how COVID-19 has had pervasive impacts across different components of the trial including recruitment, assessment, intervention delivery, and supervision. These impacts were considered to influence the external and internal scientific validity of these trials, as well as some aspects of trial administration such as budgeting and the workforce. Various mitigation strategies to adapt to constraints imposed by pandemic responses were described by researchers, such as shifting to a remote intervention delivery and evaluation or adding COVID-19 measures to better understand the impacts of COVID-19 on outcome data. The current piece provides an account of the impacts of COVID-19 on the conduct of trials of lay-delivered psychological interventions for refugees in five countries. Our findings will be valuable for researchers testing similar interventions during COVID-19 and other public health emergencies.

1. Introduction

Research on mental health and COVID-19 is rapidly growing. A living map of the evidence identified 8659 research papers on the topic of mental health and COVID-19 by January 2022 (NIHR Policy Research Programme Reviews Facility, 2022). Certain topics are receiving substantial attention, such as the impact of COVID-19 on the mental health of exposed populations, and the different responses to address these mental health consequences (Holmes et al., 2020; Kola et al., 2021). However, a topic that has not yet been the subject of substantial investigation concerns the impact that COVID-19 is having on mental health research and the way mental health research projects are being undertaken (see Mpango et al., 2020; Sarkar et al., 2020 for exceptions).

A research design that might be particularly vulnerable to methodological changes in volatile contexts is the randomised controlled trial (RCT). The RCT is a prospective study and a form of impact evaluation that seeks to evaluate two or more different intervention strategies under experimental conditions (Kendall, 2003). This is reached by strict inclusion and exclusion criteria of participants, and the use of standardised operating procedures that randomly assign participants to just one group: either a group receiving an intervention or a control group receiving an alternative, such as treatment as usual or no intervention.

However, in the context of the COVID-19 pandemic, attempts to control for additional environmental variables and continue to proceed

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as set out in trial protocols will have been challenging. For instance, there may have been challenges in recruitment of trial participants and implementing interventions that require face to face contact due to social distancing rules and travel restrictions. It is therefore to be expected that, due to their nature, including the need to minimise bias, RCT may be profoundly affected by the COVID-19 pandemic.

Initial evidence has started to emerge on several methodological challenges that COVID-19 has triggered in relation to clinical trials (McDermott and Newman, 2020), but this is not specific to mental health interventions. Issues identified concern complications with research procedures such as participants' recruitment and retention as well as with trial management (Shiely et al., 2021), remote implementation of intervention, training, and assessment (Mitchell et al., 2020), and having to suspend trials due to COVID-19 (Constable et al., 2020). Indeed, between March and April 2020 a total of 905 clinical trials registered on ClinicalTrials.gov had to be suspended due to COVID-19 (Asaad et al., 2020).

However, despite this widespread impact, most of the literature on COVID-19 and trials to date has been largely anecdotal, in the form of commentaries and opinion pieces. Additionally, very little research has focused on the impacts of COVID-19 on RCTs of psychological interventions (Myers et al., 2021), with most studies focusing on pharmacological trials. Finally, most of the research has largely focused on RCTs conducted in high-income countries, with little research on disruptions due to COVID-19 in RCTs conducted in low- and middle-income countries (Myers et al., 2021) or humanitarian settings.

The aim of the study is to explore how COVID-19 has impacted the implementation and evaluation of scalable mental health interventions for refugees and what response strategies were used to mitigate any effects. This will be achieved by providing a qualitative description of the perceived impacts of COVID-19 on 5 trials being conducted as part of the multi-country STRENGTHS project (Scaling up Psychological Interventions with Syrian Refugees). The STRENGHTS consortium represents a large project funded by Horizon Europe that aimed at strengthening mental health care systems for Syrian refugees by integrating WHO scalable psychological interventions in different countries. At the core of STRENGTHS is an evaluation of the implementation of peer-delivered psychological interventions for Syrian refugees residing in Jordan, Lebanon, the Netherlands, Switzerland, and Turkey (see Sijbrandij et al., 2017 for more information on STRENGHTS).[1]

The main intervention being evaluated in STRENGTHS is a brief, scalable, transdiagnostic intervention developed by the World Health Organization: Problem Management Plus (PM+) (Dawson et al., 2015). PM+ is being tested both in its individual format and in its group format (depending on the country site). In Lebanon, a similar programme for adolescents called Early Adolescents Skills for Emotions was evaluated (Brown et al., 2019). Additional details on intervention, setting, and populations in each setting is provided below in Table 1. While the type and structure of the RCT is the same across countries (i.e., two-armed RCTs with baseline assessment, intervention delivery, endpoint assessment, and 3- and 12-months follow-up assessments), COVID-19 affected the countries in different ways and at different stages of the RCT. These differences are described more in detail in Appendix C.

2. Methods

2.1. Participants and recruitment

All participants were active members of the STRENGTHS consortium. A purposive sampling strategy was used to identify a similar number of people across the different study countries and to cover different types of positions within the project (e.g., principal investigators, research coordinators, field coordinators etc.). Participants were contacted by email and invited to participate in the study. All potential participants that were contacted agreed to take part in the study.

Table 1
Trial characteristics.

Country	Intervention delivered	Setting in which the intervention was delivered	Population
Jordan	PM+ (group)	Refugee camp	Syrian refugees
Lebanon	EASE (group)	Mixed urban and agricultural settings	Syrian refugees
Netherlands	PM+ (individual)	Urban setting	Syrian refugees
Switzerland	PM+ (individual)	Urban setting	Arabic-speaking refugees
Turkey	PM+ (group)	Urban setting	Syrian refugees

2.2. Procedure

Qualitative semi-structured interviews were conducted with all participants. All interviews took place online using the Zoom platform. In general, interviews took place with the camera function on, but in some cases ($n = 3$), the camera had to be switched off due to broadband issues from the participant's side. No major technical issues were encountered during the semi-structured interviews. Two researchers (DM & AM) participated in most interviews (in 2 interviews only one interviewer (DM) was present). One researcher led the interview and the other researcher asked follow-up questions when appropriate. An interview topic guide was used in all interviews and is available as Appendix A. The topic guide was edited during the first interviews (i.e., questions that seemed unclear to participants were made clearer) and then remained stable across the remaining interviews. Interviews lasted an average of 1 h and were recorded. All interviews were conducted in English.

Data collection took place between February and July 2021. Ethical approval was covered by the LSHTM Research Ethics Committee. Prior to taking part in the study participants were sent an information sheet and consent form together with their email invitation, and verbal consent was confirmed and recorded at the start of the interview.

2.3. Data analysis

All 14 interviews were transcribed *verbatim* in English. Interviews were analysed using a codebook thematic analysis framework (Braun and Clarke, 2021). While transcribing the interviews, recurring themes were noted down to create a preliminary thematic framework. All transcripts were then read actively by one researcher (AM) and a subset of transcripts was also read by other members (BR, DF, AW) (two randomly selected transcripts each). This iteratively led to the construction of the coding framework that was used for the analysis (see Appendix B). We used a hybrid approach in which we focused on various deductively derived themes which we agreed *a priori* we wanted to explore in the data (e.g., impact on budget, impact on workforce) while also taking an inductive approach by focusing on new themes that were spontaneously introduced by the participants during the interview (Fereday and Muir-Cochrane, 2006). We did not use a specific theoretical framework to guide the analysis. All analyses were conducted using the NVivo 12 software. When reporting data in-text we will not name specific countries to maintain the anonymity of researchers working in specific countries given the small nature of our population, i.e., researchers in a study consortium. Additionally, details that would make a country identifiable (e.g., specific events or locations) were also removed. As a result of this we were not able to conduct cross-country

[1] STRENGHTS also included the evaluation of a digital intervention (Step-by-Step) in Germany, Egypt, and Sweden. However, given the different modality of the intervention, researchers in these countries were not included in the current study.

comparisons in the paper. Additionally, to distinguish between participants in our study and participants in the trials, we refer to participants in our study as "researchers" throughout. When the term participants is used below it indicates the trial participants. A final version of the manuscript was sent to all participants for comments.

3. Results

3.1. Researchers' and trial characteristics

Fourteen researchers agreed to take part in the current study. Researchers' characteristics are shown below in Table 2.

3.2. Impact of COVID-19 on trial

Researchers described multiple impacts of COVID-19 on different components of the trial. A summary of the overall impact of COVID-19 on the different trials is presented below in Table 3. More detailed information on the different types of impact is provided in text below.

3.3. Impact of COVID-19 on trial procedures

COVID-19 was described as having had pervasive impacts on multiple trial procedures. Recruitment of participants was hindered as researchers described struggling to recruit participants remotely in some countries. Assessment was often disrupted as the process of shifting to online modes of assessment delayed the evaluation of primary endpoints in certain countries or because some types of outcomes (e.g., biological data which required face-to-face contact) could not be collected due to national restrictions.

> "*The assessments, they were really hindered because we were doing everything up to that point, using a tablet in person, where we were able to provide feedback for them, but when, when the restriction started, we weren't actually able to enter the XXX* [setting]*, so that kind of stopped everything in terms of assessments, for the time being*"
>
> [R9]

At times, local research offices being closed during lockdowns meant that paper questionnaires from assessments could not be physically accessed. The delivery of the intervention was often most affected by national restrictions preventing face to-face contact, especially when interventions had a group format which made translation to an online format more complex. Participant retention was also impacted with some researchers reporting COVID-19-related dropouts, for example because participants did not want to move to an online form of delivery or out of concerns of COVID-19 infection if the intervention remained face-to-face. Supervision was also impacted due to restrictions around face-to-face contact.

The overall impacts varied across sites, from delays in assessments up to the need to terminate trials early. In most cases, these impacts were due to national restrictions concerning social gatherings and face-to-face interactions. In one setting, national restrictions which prohibited gatherings meant that a group intervention could not be implemented in person.

> *"For the trial and we are just unable to conduct group interventions until now, so it has been a year, yep… The schools are still closed in* [country] *and group-based activities with participants are still not allowed, so no one* [can] *gather groups of participants together"*
>
> [R13]

Restrictions at the national level often triggered temporary bans by academic institutions on research with human participants. Similarly, non-governmental organisations (NGOs) had policies forbidding workers to operate in the field and closure of office spaces where assessments may have taken place prior to COVID-19, which further affected trial conduct.

> *"We were forced by the* [name of clinic] *to stop all ongoing studies and their research projects I think until June, end of June, July, something like that, so that time, so we couldn't do anything in the time"*
>
> [R1]

The decision to stop face-to-face contact however was not always justified based on national restrictions, but also by considerations of the researchers themselves. In some cases, researchers made the argument that it would not have been ethical to put the health of both participants and trial staff at risk. Other researchers expressed concerns around the risk of legal liability if a participant got sick with COVID-19 because of their participation in the trial and the lack of insurance coverage.

> *"You're putting people at risk, and I don't know if it's worth it or not. And let's just be honest like it's a research thing so it's not something that is a priority or it's a need"*
>
> [R14]

3.4. Impact on scientific validity of the trial

The impact that COVID-19 had on different procedures of the trial was believed to have several cascading effects on the scientific validity of the trial, both in terms of external and internal validity. One researcher described how they had initially felt that "Corona's messing up the trial" as COVID-19 was pictured as an intrinsically destabilising agent that clashed with the RCT design. The RCT was perceived by researchers as being a study design particularly vulnerable to drastic shifts in context and that clashed with the unpredictable and ever-changing circumstances dictated by COVID-19. According to one researcher a "trial is so specific you don't have much opportunities for adjusting".

Table 2
Researcher characteristics.

Construct	*N* and percentage
Gender	
Men	4 (40%)
Women	10 (60%)
Role in trial	
Principal investigator	5 (36%)
Research coordinator	5 (36%)
Field coordinator	3 (21%)
Intervention facilitator	1 (7%)
Country	
Jordan	3 (21%)
Lebanon	3 (21%)
Netherlands	2 (14%)
Switzerland	3 (21%)
Turkey	3 (21%)

Table 3
Summary of impact of COVID-19 on individual trials.

Country	Impact
Jordan	Having to stop expanding the sample for the definitive RCT and having to move part of the assessment to telephone assessment
Lebanon	Had to terminate the definitive RCT early because intervention could not be delivered to the planned number of participants, but data could still be analysed. Situation in Lebanon was compounded by severe political unrest and economic downfall and by the Beirut explosion in August 2020
Netherlands	Certain parts of the trial were delayed/paused (e.g., recruitment) but trial never stopped, moving assessment online and giving trial participants the possibility to conduct PM + sessions remotely (e.g., online or via telephone)
Switzerland	Moving face to face assessments to telephone assessments, had to delay the definitive RCT, gave trial participants the possibility to conduct PM + sessions remotely (e.g., online or via telephone)
Turkey	Intervention in definitive RCT paused and then resumed, delay in concluding definitive RCT

Friction emerged between the rigid methodological and epistemological assumptions upon which the RCT was founded and the uncontrollable nature of COVID-19.

One concern expressed by a minority of researchers was around the external validity of the trial and around how generalisable the trial findings would have been given that the trial was implemented in "very unusual circumstances". While humanitarian circumstances were considered unstable by definition, COVID-19 was perceived to have amplified this turbulence in unique and complex ways.

> "*It's a concern that we're going to make, draw conclusions about the generalisability of this intervention, because we've evaluated in the context of very, very unusual circumstances. Now you can say, look whenever you're doing work in humanitarian crisis settings there's always chaos and that's true and so we're always dealing with problems.* […] *But you know you could argue that something like the pandemic is something a bit unique and you know. I think the generalisability, that is a problem*"
>
> [R10]

The more pressing threat to scientific validity mentioned by most researchers concerned the internal validity of the trial given the drastic changes that had to be made to the trial and intervention procedures because of COVID-19. One issue raised by multiple researchers concerned the fact that part of the trial had been conducted prior to COVID-19 with other parts conducted during the COVID-19 pandemic. A common concern was that the modality of the assessment had to be changed mid-trial, with assessments generally taking place face-to-face in controlled environments prior to COVID-19 and assessments during COVID-19 being conducted remotely over the phone or online. This change of assessment modality was perceived by some researchers as having possible unforeseen consequences on the way trial participants responded. For example, one researcher reported noticing that assessors were taking considerably less time to conduct the assessments online compared to the time required when the assessment was taking place in person. Even if the assessment remained in person during COVID-19, researchers reported being concerned about how the need to use masks and physical distancing may have impacted on building rapport between the assessors and the participant and the completion of the questionnaires.

> "*Even scientifically it's the way assessments are done so,* [prior to COVID] *people would come to* [physical location] *we had where assessment were done, now compare that to actually then doing it over the telephone, it's a completely different assessment tool"*
>
> [R10]

> *"A lady was doing an assessment… screening tests like that, the beginning really the beginning, and she was so tired with the mask she wasn't able to speak, and we couldn't complete, we had to stop in the middle…"*
>
> [R3]

Similarly, shifts to intervention modality were also perceived as possible threats to the internal validity of the trial. In some cases, local researchers decided to shift the intervention delivery online. Other researchers allowed participants to choose between continuing to receive the intervention face-to-face with safety measures in place such as physical distancing and face masks[2] or to move online. This meant that, in some trials, some participants had received the intervention in one modality and others in another modality. This was perceived by many as a threat to the internal validity of the trial. For some researchers, the risks to internal validity were perceived to be too high to practice this shift to remote delivery.

> *"I do not think it's the same intervention, if you are turning* XXX [intervention] *into an online remote intervention, even if we were to pull it off, I don't think you can just then just lump those samples together and say here is the outcome of* XXX [intervention]*, it's a different platform, it's a different intervention,* […] *if you change platform or format from group to individual, I think those are essentially different interventions"*
>
> [R12]

> *I don't think it's optimal that we had to shift to a fully different way of offering the intervention, so teleconferencing is obviously different than a face-to-face intervention, although it's the closest you can get, I think, but it's, it's different.* […] *So, I think that is actually impacting the validity, that we are midway, we, we have an interaction of the time plus treatment modality change, I don't like it at all, so if we would have a random treatment modality change that would have been okay, then we could compare but now it's an interaction that's also a time effect, right?"*
>
> [R5]

One participant also described how the shift to remote delivery may have impacted not only participants in the intervention group but also those in the control group.

> *"One negative effect of moving online is that people in the control group they really feel that they just answer questions over the phone and that's it, so they* [get] *nothing out of the project, they are really disappointed whereas when we still do it* [conduct assessment] *face to face, where we had to use so many resources looking back, they at least got a personal moment with an assessor and talked a bit afterwards"*
>
> [R4]

Beyond changes to modality and characteristics of assessment and intervention delivery, an additional threat to the internal validity of the trial concerned the contextual changes in participants' lives because of COVID-19. Researchers described multiple different contextual changes for participants including but not limited to mobility restrictions for refugees living in refugee camps, challenges to food distributions, limited access to health care services, difficulties with employment (especially among refugees with precarious occupations) resulting in financial problems, issues with childcare given school closure during lockdowns, and NGO activities being disrupted. Refugees were described as particularly vulnerable to the socioeconomic challenges posted by COVID-19, with one researcher highlighting how refugees had the "double disadvantage" of being refugees and living through a pandemic. According to some researchers, these contextual changes were a further threat to internal validity as the participants that had been assessed and that had received the intervention prior to COVID-19 had lived in a dramatically different world than that of those participants assessed and treated during COVID-19.

> *"*XXX [country] *is a very different place now, so you have the differences, so it's quite a different sample if you are looking at people that we are assessing in 2019 versus now, it's quite a different situation that they are living in,* […] *the economic situation for most of the families has deteriorated, so yeah I mean the lack of opportunities for work, also I think yeah just challenges with, you know, getting help from NGOs for shelter like, just like basic things were often not running during COVID…* […]*, children having even less access to school, much more violence in the communities"*
>
> [R13]

> *"I mean, one of the participants I am seeing is an old woman and she had to stay like 4 to 5 hours standing in a line* [to get food]*, this long line because of the social distancing procedures and the health protocol and so on and so "it's very hectic to me to get this bread for my kids""*
>
> [R11]

These contextual changes were thought to lead to another possible challenge to the internal validity of the trial: a worsening of mental health problems due to COVID-19 related difficulties. Most researchers

[2] Although this was perceived as possibly impacting the delivery of the intervention (e.g., reducing facial communication).

believed that the additional stressors due to COVID-19 would have resulted in increased psychological distress and mental health problems among trial participants. One researcher described how COVID-19 had "opened the door for anxiety disorders and new psychological distress to enter their [refugees] life". As mental health was the primary outcome of the RCT, this was perceived as being a substantial threat to the outcome of the trial. Most importantly, the worsening of mental health status was thought to impact the interpretation of the effect of the intervention but was also thought to have more subtle effects, such as participants possibly enrolling in the trial because of mental health difficulties experienced due to COVID-19. One researcher described how "one person said: "well I started participating because of Corona", so that is of course an effect [on the trial]".

> *"We all know that as a result of disaster your population changes. The mental health impact on the population changes as a result of disaster, now in XXX* [country] *with, and don't forget it's not just COVID, it's COVID combined with* [mentions other events] *worsened as well as this kind of political unrest. It just made for quite a pressure-cooker situation which I think you can plausibly argue has an impact on that sample, which makes that group substantially different from another, the one before in terms of descriptors, in terms of their mental health status, in terms of family dynamics, in terms of the things that XXX* [intervention] *aims to target"*
>
> [R12]

Not all researchers believed that COVID-19 had led to worsened mental health. A minority argued that prior experience with humanitarian crises and emergencies may have made the participants more prepared and resilient in facing this new stressor. Two researchers argued that some of the stressors that may have appeared novel in certain contexts such as movement restrictions would have not been that unusual for refugees living in closed refugee camp settings or refugees that had experienced political instability. Another researcher argued that increases in social cohesion during the pandemic may have made refugees feel less isolated and may have had a positive effect on their psychological wellbeing. However, this view was shared only by a minority of researchers.

> *"I would have people or patients say why are people overreacting actually, because we have been surviving in time of war, so such a pandemic is nothing. So, they would compare war to like this infection and they would say you know "I've been through much more difficult times and much more severe and adverse events and even experienced torture and so something like this it's okay, but everyone is experiencing the same not only me""*
>
> [R1]

Furthermore, some researchers, while highlighting the above-mentioned challenges concerning contextual changes due to COVID-19, also argued that the design of the RCT would have ensured that these issues had limited impacts on the outcomes of the study. The reasoning behind this was that randomisation should have ensured that contextual changes due to COVID-19 would have affected both the intervention and control group at random. As one researcher argued, one simply had to "trust randomisation".

> *"That's* [COVID-19 exposure] *in both control arm and treatment arm so… you know it cancels each other* […], *the trial accounts for it in itself by having a control group that goes through the same thing…"*
>
> [R12]

Finally, some researchers argued that, despite threats to internal validity, there were still valuable lessons that could be learned from the trial, especially as the trials focused on effectiveness.

> *"But, of course, we do an implementation study so yeah this is real life, we are, we want to be more closer to effectiveness than to efficacy, so more to real life implementation.* […] *So I still think we are still in a good situation for the study. It's not, it's not the best thing but it's yeah it's reality"*
>
> [R5]

3.5. Impact of COVID-19 on administration of the trial

In addition to having an impact on trial procedures and on the scientific validity of the trial, researchers described various impacts on the administrative aspects of the trial. Researchers described detrimental impacts of COVID-19 on the budget and on the workforce of the trial. When discussing the impact on the budget, the highest additional cost incurred due to COVID-19 concerned staff contracts as staff often had to be retained longer because of project delays and the inability to carry out face-to-face work.[3] This led to "money running out", to "burning through the money" and, in one case, contributed to the early termination of the trial – as one of several reasons (see above).

> "*Of course now that's going to put pressure on the budget because we've got people ready to go in, we've hired them, we've trained them. I've signed new MoUs* [memorandum of understanding] *between my XXX [organisation] and XXX* [NGO] *to do this, now I'm probably just going to spend through that money with those people twiddling their thumbs, and then I'm going to do another MoU and we actually, and cough up more money, you know to get it done*"
>
> [R10]

In some cases, this placed researchers in complex situations whereby they had to face what they perceived to be a dilemma between continuing to pay salaries to help maintain some income even though no work could be conducted because of the pandemic. One researcher described this as having to "balance fairness with cost" while another highlighted how "we had to make decisions, budget decisions, difficult ones…". This was made ethically even more challenging by the lack of furlough policies, in many of the countries where the trials were being implemented compounded by the dire economic situations in some contexts and by the precarious contracts of trial implementation staff.

> *I think for the first month we managed to find a way of still paying them, what they expected they would have earned in that first month, month or two, I cannot remember exactly how long it was, but then after a while it was just not feasible anymore, with like donor requirements for spending and so on, so unfortunately they were… yeah we weren't able to give them any income during that period"*
>
> [R13]

Some researchers described how budgeting decisions in the context of COVID-19 were often made more complex by donor requirements concerning how and when the money could be spent and the time delays experienced when trying to make amendments to budgets such as moving money between different cost categories (e.g., from material costs to human resources costs).

The other main impact on the administrative aspects of the trial concerned the effects of COVID-19 on the trial workforce. This was generally related to changes in working conditions experienced by the researchers including having to work from home, having to work more flexible hours (e.g., when doing telephone assessments), and having to adjust to a job that for some researchers, especially those used to work in the field, looked very different from their pre-COVID-19 job.

> "*Yeah, for everyone, after COVID-19 there is no exact working hours. And even when you are working from home, whenever you receive an email, you know what I mean, you have to reply. We were talking about the assessors for example when they called a participant and rescheduled*

[3] Some researchers also described additional costs resulting from having to purchase COVID-19 safety equipment such as face masks and hand sanitiser, but these costs were generally deemed negligible.

an appointment with them, after, let's say in 8 afternoon or 8 in the evening. So we were flexible because this is what benefits the participant but on the other hand, as XXX [organization] *staff I am working from early morning till the evening, I mean there is no exact working hours,* […] *when I have to do the assessment with this participant in the evening, and my husband came back from work, my children have some school assignments, because we have remotely also the school yeah*"

[R11]

These changes to working conditions were not always perceived as inherently negative, with some participants mentioning some positive aspects such as being able to work more flexibly, being able to spend more time with one's family at home and travelling less. However, for some researchers, these changes to working conditions were perceived as having an impact on their psychological wellbeing by fuelling feelings of isolation from one's work team and loneliness or by making it harder to concentrate on work because of distractions at home (e.g., children not at school).

"Like [prior to COVID] *when we were going back with the bus, we would just like stop somewhere and we'll just like all drink tea, sit on the grass and then do self-care so we would have that option, but right now, the only thing that I can do is just a call them and, and, you know, like ask whether everything is going well, or meeting via Zoom but it's not the same thing you know"*

[R7]

This impact on psychological wellbeing was compounded by other stressors such as the fear of being infected with COVID-19 (e.g., when conducting face to face assessments) as well as the difficulties experienced within the trial because of COVID-19. Many researchers had devoted years of their life to the trial and expressed feelings of disheartenment, lack of motivation, tiredness, and frustration because of the challenges the trial was facing due to COVID-19. For some researchers, the trial and its perceived success had become an entity to which they had become emotionally attached, with some researchers discussing how they had to "pull the plug" on the trial or "take the intervention back to life". These feelings were often further compounded by the unpredictable, novel, and uncertain nature of the situation that meant researchers often felt constantly in "waiting mode", waiting for windows of opportunity to re-start the intervention face to face, constantly having to re-adjust to an ever-changing situation and having to "live day by day". Researchers expressed frustration at the realisation that something that had been so meticulously planned across many years ultimately came down to being dependent on luck and contingency, such as the time of COVID-19 waves in specific countries.

"Yeah I think as, I think it's disheartening for everyone […]*, you know, like everyone has been working, I mean a lot of us have been working,… with the trial, since 2017,…, so, you know working on first like the needs assessment, then the cultural adaptation, then developing all the measures and doing the pilot trial, and then like doing the big trial and then we are all like "oh, we didn't even… we don't get to finish it",…, so I think that has been disheartening for everyone,…, and then you know having to tell everyone in the organisation that we are not going to finish it and yeah it has been challenging, also because everyone is eagerly awaiting the results but you know"*

[R13]

"Then I got really demotivated for our trial, because the first time… that was a really big disappointment, especially at that moment because I couldn't oversee the bigger picture, […] *It was really insecure….ok can we start it again in September or not* […] *but then again measures got stricter, so that was postponed a little bit again* […] *then I really thought "Ok, now we can give up the trial""*

[R4]

Various strategies were put in place by some teams to support the psychological wellbeing of the trial workforce. In particular, efforts were made to try and ensure that effective communication was maintained within the team. This was done by scheduling regular daily or weekly meetings within the team, by keeping remote channels of communication open (e.g., creating WhatsApp group chats), and by trying to be more proactive with checking in on members of the team.

"*We really tried to have daily check-ins every morning and just to have coffee and to have a casual chat which I think was nice, I definitely appreciated that myself*"

[R13]

However, most researchers believed keeping up effective communication and building rapport between team members was more challenging online compared to face-to-face and required extra effort. This was particularly problematic when researchers in different countries had never worked with each other, so rapport and trust were perceived as being more challenging to build online.

"So much of these projects are done via relationships and so when I go to a place like XXX [country] *it's when you know we will sit down with the directors, you know the organisations and the workers and they you know it's a very Arabic thing to do, but you know they will you know it's over coffee and baklava are, and you know all that kind of stuff and you know they will be the host and we will talk and you know this is how things are done and trust is built, one cannot do that over Zoom"*

[R10]

Importantly, while researchers mentioned negative impacts of COVID-19 and related stressors on their psychological wellbeing, some also reported silver linings to this experience such as being satisfied with how they had managed to deal with a complex situation, having learned new skills on both a personal and professional level, or feeling like they had grown closer with certain team members.

3.6. Strategies to mitigate impact of COVID-19

Despite the multiple challenges experienced due to COVID-19, various mitigation strategies were put in place. As one researcher stated: "COVID you cannot solve it, for the project, but we were able to manage it". The most common strategy to mitigate the impacts of COVID-19 was moving components of the trial to a remote modality. Every country reported to moving the assessment component of the trial to a remote modality, either conducting assessments via phone or via an online platform. Conversely, countries took different stances around moving the intervention delivery to a remote modality with some countries allowing participants to choose between face-to-face and remote modalities. However other countries, especially those with group-based interventions and/or in settings with poor Internet connections, considered the shift to a remote modality unfeasible and decided not to implement this strategy.

As described above, the shift to a remote modality was generally based on national restrictions banning group gatherings or face-to-face contacts but some researchers also mentioned ethical reasons, such as protecting the safety of participants and researchers. One participant highlighted how this ethical argument was compounded by the fact that participants may have come to face-to-face assessments or intervention sessions even if scared of COVID-19 just to receive the small compensation provided to trial participants in some countries. A further ethical argument behind the shift to remote was that of ensuring that participants could still receive some form of psychological support during the pandemic. This led some researchers to express concerns when they were not able to shift the intervention to a remote modality with one researcher describing how "there was a promise that we were not able to meet".

The shift to remote was described by participants as holding multiple practical and ethical challenges. Researchers mentioned various

practical and logistical issues including participants not having access to laptops or smart phones (or having only one device per family), lack of Internet in refugee camps or in reception centres for refugees, facilitators not living in a setting that allowed them to do online intervention sessions (e.g., crowded housing), participants lacking the financial means to buy phone credit or not being able to renew their phone credits during lockdowns, participants being on the move and changing phone numbers, as well as some participants being less digitally savvy. This led one researcher to define the process of conducting remote assessments in a refugee camp a "logistical nightmare". In one case, the lack of mobile phones was solved by having one researcher borrow a mobile phone of an NGO to be used by different families in a refugee camp. Additional practical challenges included people getting distracted during long remote assessments, as well as certain instruments being challenging to administer remotely (e.g., lengthy instruments).

> *"The challenges of that is that a lot of areas we had, for example, the families did not originally have a phone cell, they just give the phone cell of the community leader there, who is not very helpful as well at all times, and a lot of people have moved or their line has closed because they were not able to recharge their lines, didn't have money"*
>
> [R14]

> *"Because in some cases for example, household wife, when we call her she said "ok I have to cook for my children, I have my baby is crying, shall I call you again?" so we had to cut and continue the conversation again, you know, we had to have the one assessment session we had to divide it in 2 sessions or 3 sessions maybe, depends on the case, for some they were saying "ok we are in Ramadan and we have some rituals in Ramadan" and they were saying "ok I cannot talk right now because I have to do this and that", for example"*
>
> [R11]

In addition to practical and logistical challenges, researchers also mentioned various ethical challenges concerning the shift to remote. These included issues around confidentiality and selecting an online platform or software that was in line with ethical requirements such as General Data Protection Regulation (GDPR), ensuring appropriate safeguarding and follow-up procedures (e.g., how to respond promptly in case participants screened positive for suicidal ideation or reported an adverse event during assessments and intervention sessions), problems with privacy when participants lived in crowded spaces, and complications in obtaining written informed consent. In one case, these issues meant that the trial was delayed because of the need to go through multiple amendments with the ethics committee. Some of these issues were mitigated by providing additional training to accessors and facilitators in how to properly conduct assessments and/or intervention sessions remotely.

> *"Typically, every family has a phone in these countries, but they share them. Now, when they're living in a little apartment or in a caravan or refugee camp issues of privacy become huge, because how do you assess somebody about personal you know matters like psychological functioning or things like that and you know they've got their brothers and sisters all standing around them, you know listening, sort of, it's ethically and scientifically, a bit challenging"*
>
> [R10]

In some instances, these practical and ethical challenges were perceived as insurmountable, especially when they concerned shifting group interventions to a remote modality, with researchers describing this shift as "impossible" in certain settings.

> *"This is a group XXX* [intervention], *we first thought about it, can do these groups through phones, WhatsApp, you know this kind of Zoom. But then we cannot guarantee the confidential because, as you may expect, most Syrians are living in crowded houses and there will be a confidentiality issue or technical issues, they may not be able to have this Internet and these things so and this actually kind of give a break, postponed this group XXX* [intervention] *implementation for a while"*
>
> [R6]

While researchers mentioned multiple practical and ethical issues surrounding the shift to remote, some also mentioned various advantages. According to most researchers, shifting assessments online was relatively straightforward and had various advantages including reducing travel costs, making data collection more straightforward when data were collected over an online platform, and allowing the study to expand its reach (e.g., reaching participants that would not be able to regularly attend in person). This led some researchers to state that they would likely retain remote assessment in future trials. Some of the researchers who moved the intervention delivery to a remote modality highlighted how this had also made the intervention more accessible to participants, but this point was often context specific.

> *"But yeah, I think we actually are happy with some of the changes, so with assessing people it's much better to do it online, I think in the end"*
>
> [R5]

> *"But I think it's way more feasible* [to have intervention sessions online] *than having people come in every week for a session, especially if they have some other sort of disability, I mean now we have people in wheelchairs and people with chronic diseases and for them it's just too stressful to take a XXX* [mentions type of public transport] *and come to XXX* [city] *just for one and a half hours and they might even have to take the XXX* [type of public transport] *for two hours to get here, so it doesn't, it doesn't add up"*
>
> [R2]

Another common mitigation strategy reported by researchers was that of including a COVID-19 measure in the follow-up assessments. This COVID-19 measure generally covered COVID-19 exposure (i.e., whether the participant or a family member had got infected with COVID-19), the psychological impacts of COVID-19 (e.g., how anxious the participant had been due to COVID-19 related stressors such as fear of infection or lockdowns), as well as the socio-economic impacts of COVID-19 (e.g., in terms of finances, access to food etc.). Most researchers described how this measure could be included in the quantitative analyses to try and explore the impact of COVID-19 on outcomes. This was described by researchers as trying to "control for" COVID-19.

> "*We do have obviously a COVID measure that we put into the assessments. I don't know how we're going to integrate that in into the analysis, whether we just use that as, as moving continuous scale to see the interaction there, or what we're going to do so, hopefully we'll be able to elucidate a few of those impacts,* […] *something like a COVID measure as a modifier and just see how that impacts, the* […] *people, whether there's a subgroup*"
>
> [R9]

This was part of a more general narrative concerning statistical mitigation strategies to understand the impact of COVID-19 on the trial. Researchers described various statistical strategies such as controlling for time, looking at the relationship between the COVID-19 measure and mental health outcomes, doing sensitivity analyses, or calculating inter-reliability rates between participants that had completed assessments or received the intervention using different modalities. These techniques were believed by some to "account for" COVID-19, "take the effect [of COVID-19] out of the research", and to "limit or to split the effect of COVID-19 on the research in order to get the right results". One participant expressed scepticism towards these statistical solutions arguing that "it's just going to be hard to control for that", especially given the complex interactions taking place between COVID-19 and other socio-political stressors of humanitarian settings such as political instability and economic stagnation. A minority of participants described process evaluations and qualitative interviews as additional

tools to capture and understand the impact of COVID-19 on the trial.

> *"Through sensitivity analysis or sub-group analysis you can account for that in your analysis right? you can say well what if your pre-COVID waves and your post-COVID waves and then through sensitivity analysis actually see well do we see any differential changes, so…* […] *I think that statistically there is really good ways around it"*
>
> [R12]

> "*I think one of the things is when we're going into it, a lot of the questions that you've asked today will be integrated into the process evaluation some way about how did the COVID pandemic affect day to day, was school still available, were you able to go to the all the community centers, were you able to access health care*"
>
> [R9]

A final mitigation strategy described by researchers to limit the impacts of COVID-19 was that of taking infection prevention strategies. This included calling people before face-to-face assessments or intervention sessions to check for COVID-19 symptoms, providing masks and hand sanitisers to participants, as well as enforcing physical distancing regulations, doing assessments outdoors, or paying for the fuel of intervention facilitators so that they could travel with their own cars rather than using public transportation. In one country, researchers decided to hold the group intervention sessions in an open-air terrace of a building to ensure physical distancing and appropriate ventilation measures.

4. Discussion

This paper presents a unique case study concerning the impacts of COVID-19 on five randomised controlled trials of brief psychological interventions for refugees in a diverse set of high- and middle-income countries. COVID-19 was perceived as having profound impacts on multiple components of the trials from recruitment to supervision. This is in line with global evidence on the impacts of COVID-19 on clinical trials highlighting how clinical trials have experienced significant delays in timelines, drastic deviations from protocols, and in some cases a complete halting of research procedures (Chen et al., 2021; Sathian et al., 2020). However, the vast majority of this evidence comes from HICs and from pharmacological trials (Myers et al., 2021), meaning that our paper contributes to filling an important gap in the literature around the impacts of COVID-19 on trials of psychological interventions and public health interventions conducted in middle-income countries (MICs) and humanitarian settings. While many of the challenges reported in the current paper are shared with HIC settings, others are more likely to be unique to humanitarian settings and MICs, such as the impossibility of accessing closed refugee camps due to national lockdowns or the critical impacts of social determinants resulting from COVID-19 (e.g., poverty, unemployment, food shortages, insecurity, and inadequate housing).

The impacts on the trial were, in some cases, perceived by researchers to have implications on the scientific validity of the trial. The risks that COVID-19 poses to the scientific integrity of trials have also been the object of discussion in the wider clinical research literature (Akacha et al., 2020; Fleming et al., 2020; McDermott and Newman, 2020). COVID-19 indeed represents what has been termed a "history effect"; an event that can change how individuals and study groups respond to interventions, threatening the internal and external validity of the trial (Mara and Peugh, 2020). Threats identified by researchers in our study included possible impacts on primary outcomes due to increased stress, changing modalities of intervention delivery and assessment with potential measurement mode effects (Hox et al., 2015), and contextual changes in participants' lives related to COVID-19.

Other threats identified in the literature also include differential drop-out (e.g., participants with less access to Internet or electronic devices being less likely to engage in online delivery or being less likely to participate face-to-face if living with pre-existing health conditions), selection bias (e.g., online recruitment excluding participants from certain demographics), and, in the case of trials with youth, maturation (i.e., participants experiencing meaningful developmental changes while the trial is paused or delayed) (Mara and Peugh, 2020). Some of these threats are likely to be profound when working with vulnerable populations such as refugees, meaning that even more attention should be paid to these threats in the context of similar trials. For example, researchers highlighted how the lives of refugees were disproportionately impacted by COVID-19 with multiple challenges from disrupted food distribution in refugee camps to increased job insecurity. This is backed by empirical data showing how, in Turkey, debt levels in refugee households increased by nearly 50% during COVID-19 with many families unable to pay for food (72%) or rent (66%) during the pandemic (International Federation of Red Cross, 2021). Given the likely impacts of these challenges on mental health, clinical trials working with similar populations should collect data on these changes and consider their impact on the trial outcomes.

Importantly, researchers described some strategies that had been put in place to mitigate the impacts of COVID-19 on the trial such as shifting assessments or intervention sessions to a remote modality or the inclusion of new measures to better understand the possible impacts of COVID-19 on the trial results. The shift to remote modes of assessment and intervention delivery has also been highlighted in multiple other clinical trials (Chen et al., 2021) and has also been advised in certain cases by formal guidance documents on the conduct of clinical trials during COVID-19 (European Medicines Agency, 2020; US Food and Drug Administration, 2020). In general, substantial guidance has been developed on how to mitigate the impacts of COVID-19 on clinical trials, including guidance on statistical techniques (Fleming et al., 2020; Mara and Peugh, 2020; Meyer et al., 2020), safety procedures (Krueger et al., 2021), as well as data collection and intervention delivery (McDermott and Newman, 2020).

However, most of the existing guidance relates to pharmacological trials and has been developed with trials conducted in HIC in mind. As a result, some of the mitigation strategies advised in this guidance may be less relevant when implementing psychological interventions or might need adaptation when working with specific populations such as refugees living in MICs (Myers et al., 2021). For example, shifting to remote modes of assessment and intervention delivery, a common mitigation strategy included in COVID-19 clinical trials guidance, was fraught with practical and ethical complexity in the contexts where the trials described in this paper took place, with researchers describing the process as very difficult. Trial participants often did not have access to the Internet and technological devices, or they lived in crowded housing where confidentiality could not be ensured. Similar issues were noted in a feasibility trial of a psychological intervention conducted among South African adolescents (Myers et al., 2021). Therefore, there is a need for more context specific guidance tailored to the specific challenges of COVID-19 for clinical trials conducted among vulnerable populations such as refugees (e.g. see Chen et al., 2021; Singh et al., 2021 for two examples of guidance on remote data collection among refugees) and aimed at improved measurement of implementation failures.

Beyond impacts on the scientific validity of the trial, researchers also reported various impacts on the administrative aspects of the trial such as the budget and the workforce. This included having to extend staff contracts due to delays in the conduct of the trial, as well as changes to working conditions for trial staff, with subsequent impacts on their psychological wellbeing. To date, most of the guidance on COVID-19 and clinical trials has largely focused on scientific and technical aspects, with less literature focusing on the experiences of researchers working on trials during COVID-19. The current study highlights that COVID-19 had significant impacts on the personal lives of the researchers, from job insecurity to feelings of frustration, demotivation, and tiredness. Some researchers however also reported remaining motivated because of considerable efforts to maintain communication

channels open.

While we did not use a specific theoretical framework to guide the interpretation of these findings, our results align well with the Consolidated Framework for Implementation Research (CFIR). The CFIR is a widely used implementation framework used to inform the design, evaluation, and implementation of evidence-base interventions (Safaeinili et al., 2020). The CFIR comprises five different domains including: intervention characteristics, outer setting, inner setting, characteristics of individuals, and process of implementation. Fig. 1 below outlines how some of our findings map onto the different CFIR domains.

Various practical recommendations can be extrapolated from the findings. Firstly, practical strategies should be developed by donors and governments to ensure greater flexibility in financial mechanisms in place to protect researchers in unstable job contracts when similar events take place (e.g., facilitating moving resources between different budget categories to prioritise the protection of human resources or ensuring furlough schemes for researchers). The feasibility of establishing insurance schemes to safeguards against the consequences for research projects of these events can also be explored by research funders. Additionally, the current piece highlights the importance of flexibility and support by research funders and ethical committees in continuing implementation of RCTs during unforeseen contextual changes like pandemics.

Furthermore, given the complexity of planning for such events and the highly context specific impacts of similar events on the trial, it is key to collect mixed methods data concerning protocol deviations and implementation challenges. Process evaluations are likely to be particularly valuable in this endeavour. Such process data can play a key role in ensuring that deviations from the protocol and contextual influences on the trial are accounted for in the interpretation of the findings and are likely to be even more valuable during COVID-19 given the possible impacts on the pandemic on the trial implementation context (Moore et al., 2015).

Additionally, contingency plans should be considered by researchers when planning on conducting research in complex settings. This could include considering different options for assessment or different intervention modalities if it becomes unfeasible to meet participants in-person. Digital tools are likely to be particularly helpful when considering different options for both assessment and intervention implementation in crisis settings (Javakhishvili et al., 2023), while bearing in mind ethical issues to digital mental health such as ease of access or the digital divide. Other additional practical considerations that researchers can take away from this paper include diversifying recruitment strategies, having reliable ways of measuring exposure to unexpected stressors (e.g., COVID-19) to include as a confounder in the quantitative analyses if relevant, consider the ethical implications towards participants whose mental health may worsen during the trial because of external stressors, and plan for possible logistical challenges when moving to remote modalities such as budgeting for the provision of phone or Internet credit to participants.

Finally, trial principal investigators should be aware of the importance of supporting the wellbeing of the workforce during similar events (e.g., by ensuring effective communication takes place despite lack of face-to-face contact). We believe that safeguarding the wellbeing of researchers should receive just as much attention as concerns over the scientific validity of trials, especially for local researchers with precarious contracts working and living in high-risk settings (Sukarieh and Tannock, 2019).

The current study has various limitations. Data collection took place over six months meaning that researchers were interviewed at different stages of the COVID-19 pandemic. However, we tried to interview researchers from the same country during the same period to reduce this risk within a country. A second limitation is that one of the interviewers was part of the STRENGTHS trial consortium meaning that some researchers may have been more wary about sharing sensitive information. However, another researcher not involved in the STRENGTHS consortium was also present in most interviews and analysed the data to reduce the possibility of bias in the interpretation of the data. Additionally, the participation of members of the STRENGHTS consortium can also be seen as a strength as it ensured that data from the interviews could be triangulated with objective knowledge of how the trial had been conducted and increased credibility. Furthermore, interviews took place only in English, meaning that local researchers in more operational positions such as assessors who would have generally spoken only the local language are under-represented in our sample. However, we did manage to still include the perspective of three local field coordinators and one local intervention facilitator. Moreover, the decision not to name specific countries in our results to ensure anonymity limited our ability to draw cross-country comparisons. Finally, our findings are limited by the small sample size, but this was a direct result of our small research population, i.e., the workforce of a clinical trial.

5. Conclusion

The current study contributes to the literature on the impact of COVID-19 on clinical trials by detailing impacts and mitigation strategies in the context of five RCTs of psychological interventions for Syrian refugees in five countries in a small sample of researchers. The focus on psychological interventions and refugees as well as the inclusion of trials

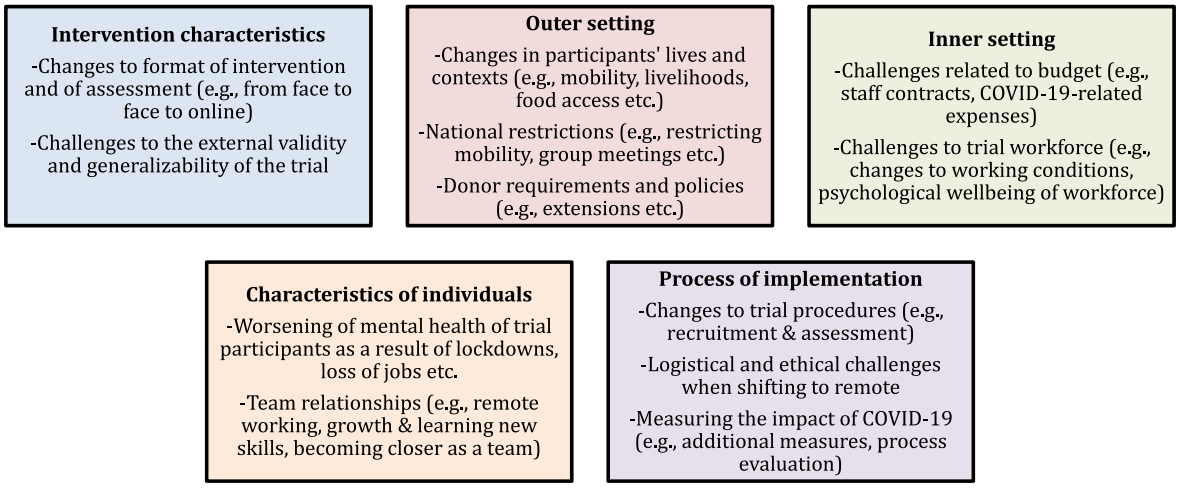

Fig. 1. Results framed within the Consolidated Framework for Implementation Research (CFIR).

conducted in high- and middle-income countries differentiate the current study in the context of a literature that has to date largely focused on the impacts of COVID-19 on pharmacological trials conducted in HICs. This study contributes to knowledge on how COVID-19 may influence trial procedures, administration, and scientific validity in the context of lay-delivered psychological interventions for refugees. We hope that by sharing lessons learnt and strategies used to address COVID-19, this paper will be of use to other researchers when considering mitigation measures against future external events, such as future pandemics waves, and when planning and conducting clinical trials in similar settings and with similar populations.

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Availability of data and materials

The data will be not publicly available due to information that may compromise the privacy of research participants.

Ethics approval and consent to participate

The study was approved by LSHTM Research Ethics Committee. Participants who agreed to participate were asked to digitally sign their names and return the consent form via email to the interviewer.

Consent for publication

Not applicable.

CRediT authorship contribution statement

Alessandro Massazza: Conceptualization, Formal analysis, Methodology, Writing. **Bayard Roberts:** Conceptualization, Writing, Supervision. **Daniela C. Fuhr:** Conceptualization, Writing. **Aniek Woodward:** Conceptualization, Writing. **A-La Park:** Conceptualization, Writing. **Egbert Sondorp:** Conceptualization, Writing. **David McDaid:** Conceptualization, Methodology, Writing, Supervision.

Declaration of competing interest

The authors declare no competing interests.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ssmmh.2023.100251.

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