


# BMJ Open Digital health literacy intervention to support maternal, child and family health in primary healthcare settings of Pakistan during the age of coronavirus: study protocol for a randomised controlled trial

Sara Rizvi Jafree,<sup>1</sup> Nadia Bukhari,<sup>2</sup> Anam Muzamill,<sup>3</sup> Faiza Tasneem,<sup>4</sup> Florian Fischer <sup>5,6</sup>

**To cite:** Jafree SR, Bukhari N, Muzamill A, *et al*. Digital health literacy intervention to support maternal, child and family health in primary healthcare settings of Pakistan during the age of coronavirus: study protocol for a randomised controlled trial. *BMJ Open* 2021;**11**:e045163. doi:10.1136/bmjopen-2020-045163

► Prepublication history and additional material for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2020-045163>).

Received 25 September 2020  
Revised 15 February 2021  
Accepted 23 February 2021



© Author(s) (or their employer(s)) 2021. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

For numbered affiliations see end of article.

## Correspondence to

Dr Florian Fischer;  
florian.fischer1@charite.de

## ABSTRACT

**Introduction** There is a need to continue primary healthcare services through digital communication for disadvantaged women living in underdeveloped areas of Pakistan, especially in the age of the coronavirus pandemic, social distancing and lockdown of communities. This project will be the first of its kind in aiming to implement a digital health literacy intervention, using smartphone and internet, to disadvantaged women through female community healthcare workers. Improved health literacy in women of reproductive years is known to promote maternal, child and family health overall.

**Methods and analysis** The study will include a baseline survey, a pre- and post-test survey and a 3-month lasting intervention on (1) hygiene and prevention and (2) coronavirus awareness and prevention. Women of reproductive years will be sampled from disadvantaged areas across the four provinces of Pakistan (Baluchistan, Khyber Pakhtunkhwa, Punjab and Sindh), and the selection criteria will be poor, semiliterate or illiterate, belonging to underdeveloped neighbourhoods devoid of universal healthcare coverage and dependent on free primary health services. A target of 1000 women will comprise the sample, with 500 women each assigned randomly to the intervention and control groups. Analysis of variance and multivariate analysis will be used for analysing the intervention's effects compared with the control group.

**Ethics and dissemination** Ethics approval for this study has been received from the Internal Review Board of the Forman Christian College University (reference number: IRB-252/06-2020). Results will be published in academic journals of repute and dissemination to the international scientific community and stakeholders will also be planned through workshops.

**Trial registration number** NCT04603092.

## INTRODUCTION

South Asia is home to 25% of the world population, the majority of who are poor and without universal health coverage. Research

## Strengths and limitations of this study

- This is the first randomised controlled trial in Pakistan investigating the effects of a digital health literacy intervention for hygiene and sanitation, and coronavirus awareness and prevention, tailored to the needs of disadvantaged women of reproductive years.
- We aim to use a two-step approach to pretesting and then establishing an intervention; the findings will be relevant for digital health literacy interventions in general, but particularly in times of the coronavirus pandemic, where social distancing hinders the provision of health services to women dependent on primary health services in their community.
- The study will be an important contribution to the knowledge about efficacy of digital health literacy interventions to support sustainable development goals for maternal and child health.
- We anticipate cultural barriers in gaining permission for women's participation in the study and the engagement with smartphones and internet, especially in more conservative and inaccessible regions.
- There are limitations to generalisability due to potential bias from including women who gave consent to participate in the study and also because outcomes will be measured based on subjective perceptions of respondents.

has estimated that 1 in 10 South Asians face health challenges, multimorbidity and risk of infectious disease; with each additional morbidity carrying greater risk of mortality.<sup>1,2</sup> Pakistan's healthcare sector is known to be under-resourced and inefficient, with health budget allocation standing at less than 1.5% of gross domestic product.<sup>3</sup> Primary healthcare services in Pakistan are not adequate or well planned, contributing to the infectious



disease burden in the country and unfavourable indicators for maternal and child health.<sup>4</sup> There is critical need for more integrated and innovative planning for primary health services, where identification of diseases, treatment referrals and prevention is possible. According to its number of inhabitants, Pakistan is the sixth largest country worldwide,<sup>5</sup> with more than a 100 million women living there. Local research has confirmed that women in the country are suffering from a quadruple disease burden of (1) communicable/infectious diseases, (2) non-communicable diseases, (3) accidents, injuries and violence, and (4) multimorbidity.<sup>6,7</sup> Additionally, women from lower and middle-income countries (LMIC) may suffer from health challenges and infection risk more than men.<sup>1</sup> It has also been estimated that women from unfavourable sociodemographic backgrounds and living in deprived areas experience health challenges and multimorbidity 15 years earlier than people from more affluent backgrounds.<sup>8</sup>

An additional and important consideration is that women from Pakistan suffer from regressive cultural norms and community neglect. This is why most women in Pakistan are unemployed,<sup>9</sup> illiterate or semiliterate, crippled by poverty<sup>6</sup> and thus increasingly vulnerable to multiple health burdens. Several sociocultural burdens adversely influence the health of women of reproductive years in Pakistan, including low health literacy, undernutrition, early marriage, lack of birth spacing and a culture that prevents health-seeking behaviour. Though it is assumed that health challenges affect people at more advanced years, pregnant women in LMICs are at an increased risk of health burdens and infectious diseases.<sup>1,2,10</sup> Pregnant women are not merely at risk of mortality themselves, but there is concern that their child is also at heightened risk.<sup>11</sup>

The greatest concern for LMICs and Pakistan is that women of reproductive years who are illiterate and semiliterate are not able to manage health, or adopt protective behaviour, due to lack of awareness and education, and difficulty in understanding instructions by physicians or public health experts. Research suggests that health services provided to women of reproductive years in the country are insufficient at both primary and tertiary levels.<sup>12</sup> In the age of coronavirus, services have been further compromised due to enforced social distancing. It is critical that women are provided urgent assistance for infection protection, symptom management and health access during the pandemic.<sup>13,14</sup> There is no doubt that promoting digital health literacy must be the first step of intervention to support disadvantaged women of reproductive years in managing their health in times of social distancing.<sup>15</sup> Disadvantaged women are defined within this study as those who are (1) from the lower wealth strata, with low levels of literacy, and from underdeveloped neighbourhoods, (2) unable to afford private healthcare and private health insurance, and (3) dependent on free primary healthcare services delivered within their community.<sup>16</sup>

## Aim of the study

The study's aim is to develop and implement a digital health literacy intervention to disadvantaged women in the areas of (1) hygiene and sanitation and (2) coronavirus awareness and prevention. The study includes a baseline survey and a pre- and post-test survey. The 3-month lasting digital health literacy intervention, using a smartphone and internet, will include four components of (A) video tutorials, (B) one-on-one training for improving awareness and practices, (C) group training, and (D) one-on-one training for a self-management chart. The data will be collected by community healthcare workers and the participants of this study will be disadvantaged women, defined as poor, semiliterate or illiterate and belonging to underdeveloped neighbourhoods devoid of universal healthcare coverage and dependent on free primary health services.

## METHODS

### Study design

A randomised controlled trial (RCT) will be conducted providing a digital health literacy intervention for (1) hygiene and sanitation and (2) coronavirus awareness and prevention. A summary of the proposed steps and the timeline is provided in [table 1](#). We expect to conclude the study within 5 months, with a cushion of 15 days. The study follows three consecutive steps. At the first step, baseline data will be collected about the health challenges faced by women living in disadvantaged communities. At the second step, a pretest survey will be administered to both the control and intervention groups assessing their health literacy. A health literacy booklet will be provided to both the control and intervention groups after the pretest. In addition, the intervention group will receive an intervention using digital means, smartphone and internet, through a 3-month period for promoting health literacy related to: (1) hygiene and sanitation and (2) coronavirus awareness and prevention. At third and final step, both the control and intervention groups will be delivered a post-test to assess the differences between intervention and non-intervention groups.

The specific study hypotheses are that there is a positive impact of the digital health literacy intervention on the intervention group (disadvantaged women of reproductive age in Pakistan) with regard to improvements in: (H1) hygiene and sanitation and (H2) coronavirus awareness and prevention. This study protocol follows the 'Standard Protocol Items: Recommendations for Interventional Trials' checklist (online supplemental file 1).

### Ethics of research

Ethics approval has been taken from the Internal Review Board of the Forman Christian College University (IRB approval reference IRB-252/06-2020). Informed consent will be taken from all participants (online supplemental file 2). A cover letter will be provided and read out to the participants. Contact information of the principal

**Table 1** Data collection schedule

	1. Baseline survey	2. Pre-test survey	3. Health literacy booklet distribution	4. Intervention delivery		5. Post-test survey
			Video tutorials	One-on-one training for improving awareness and practices	Group training	One-on-one training for a self-management chart
Date	7 days: January 2021	7 days: January 2021	90 days: February to April 2021	7 days: January 2021	7 days: February to April 2021	7 days: May 2021
Control group (n=500)	✓	✓	✓	✓	✓	✓
Experiment (n=500)	✓	✓	✓	✓	✓	✓
Weekly training/discussion				✓		✓
Monthly training/discussion			✓		✓	
Training covers hygiene and sanitation			✓	✓	✓	✓
Training covers coronavirus awareness and prevention			✓	✓	✓	✓
Possibility to consult with healthcare specialist (female doctor, pharmacist)				✓		

**Table 2** Sampling strategy

Province	Population weightage (%)	Total sample*	Intervention	Control	CHWs for data collection and intervention delivery
Punjab	52.95	550	275	275	55
Sindh	23.04	250	125	125	25
Baluchistan	5.94	100	50	50	10
KPK	14.69	50	25	25	5
Total		1000	500	500	100

\*Absolute sample figures have been rounded off.

CHWs, community healthcare workers; KPK, Khyber Pakhtunkhwa.

investigator will be provided along with possibility of free counselling services in case of any emotional disturbance caused by the discussion of health challenges. No personal information will be taken and anonymity and confidentiality will be maintained. Only female community healthcare workers will be responsible for collecting data from the women. Timing for data collection and intervention delivery will be sought from participants in advance to ensure privacy and comfort of women. All participants will be free to withdraw from the study at any time.

### Study population

The study population will comprise all disadvantaged women of reproductive age (15–45 years). Women not of reproductive age will be excluded from the sample. Given that there are 110 million women in Pakistan, using the Taro Yamane's formula,<sup>17</sup> we need to sample an approximate 399 women each for the control and intervention groups. Considering the possibility of dropouts, we target to sample a total of 1000 women: 500 for the control group and 500 for the intervention group (table 2). We have chosen the Taro sampling formulae as we anticipate difficulties in seeking permission for participation in a digital health literacy intervention among poor disadvantaged women. This is because women from disadvantaged communities belong to highly conservative and patriarchal families in Pakistan and are entirely dependent on their husband, in-laws and family for permission with regard to participation in research and access to digital technologies. Probability sampling will be adopted in communities to allow equal chance of selection.<sup>18</sup> A nationwide database from government sources will be used to randomly select participants from underprivileged communities who depend on primary healthcare services according to provincial population weightage. All four provinces of Pakistan (Baluchistan, Khyber Pakhtunkhwa (KPK), Sindh and Punjab) will be sampled according to their population weightage.

### Data collectors

Pakistan has a well-established Lady Healthcare Worker Programme with over 110 000 functional women providing healthcare services across communities in Pakistan for primary healthcare.<sup>19</sup> Services provided by community healthcare workers are mainly related to

maternal and child health, immunisation and vaccination.<sup>20</sup> Community healthcare workers are either directly employed by the government or managed through outsourcing or contracting of private sector.<sup>21</sup> For this study, the data will be collected and intervention will be administered by hiring existing community healthcare workers, assisted by both the government and private sector. They will have a minimum 1 year of working experience in delivering primary healthcare services in the community. Each community healthcare worker will oversee 10 study participants (five each from intervention and control groups), which would mean 100 community healthcare workers will be recruited for this project. Over a 2-week period, the community healthcare workers will be trained for this project and its research objectives via Zoom meetings.

The community healthcare workers will also be provided a 3-day training on the use of digital technology and related software, including an interactive practice session. In turn, the community healthcare workers will be responsible for training the participants in three meetings, targeted to be completed in 1 week. All community health workers will be provided weekly supply of masks and hand sanitisers to cover expected daily needs. They will have the provision to contact their respective field coordinator if they run low on supplies. Before the intervention, the community health workers will receive a 1-day group training on safety measures and protocols for COVID-19 by a trained female doctor. A training venue within each district will be reserved for this activity. We plan to sample six districts in this study, and each district will have approximately 15–20 community health workers.

### Baseline, pre- and post-test

The baseline survey will be used for data collection about the overall health status of sampled women (online supplemental appendix 1). It has been developed using a standardised and validated scale, which is the 'Multi-morbidity Assessment Questionnaire for Primary Care'.<sup>22</sup> The six domains covered in this scale are: (1) sociodemographic characteristics, (2) healthcare utilisation, (3) chronic diseases, (4) depression, (5) disease severity, and (6) health-related quality of life. The pre-test and post-test surveys for the intervention have been developed using

select items from standardised questionnaires, including (1) 'Health Education Impact Questionnaire',<sup>23</sup> (2) 'The National Sanitation and Hygiene Knowledge, Attitudes, and Practices Survey', and (3) 'The Community-Based Assessment of Knowledge, Attitude, Practices and Risk Factors Regarding COVID-19'<sup>24</sup> (online supplemental appendix 2). Both surveys measure the perceptions of respondents and record answers on a 5-point Likert scale. The primary outcome for this study will be the positive and active changes in health-directed behaviour, engagement with life and self-monitoring and insight to monitor health conditions. The secondary outcomes will be improvement in social integration and support and emotional well-being and satisfaction with life.

### Health literacy booklet

The control and intervention groups will both be provided a health literacy booklet after the pretest (online supplemental appendix 3). The health literacy booklet will include images and content related to: (1) hygiene and sanitation, and (2) coronavirus awareness and prevention. The booklet will include literacy about hygiene, sanitation and coronavirus prevention that have already been circulating on TV, radio, newspapers and other social media sources. The attempt will be to reinforce and highlight health and infection control information to women. The hard copy of the booklet will encourage women to retain and adopt information by circulating within household family members. The material is in line with international health communication standards. Pictures will be taken from valid and reliable sources including Government of Pakistan, WHO and United Nations and cited accordingly. The booklet will be delivered at the doorstep of the female participants. Women will be asked to retrieve the material after 5 min of the delivery to secure social distancing during the coronavirus pandemic.

### Digital health literacy intervention

The health literacy intervention is guided by previous research and carefully considers the following: (1) the literacy and semiliteracy of participants, (2) the social context of female participants related to their role and relationship with their family, husband, in-laws and community, and (3) the sociodemographic characteristics of participants, such as their residence, income, home responsibilities, working status, time and energy for intervention and ability to change their lifestyle. Participants in the intervention group will be delivered the intervention through a smartphone and internet, managed by the community healthcare workers including instructions for the intervention. During the intervention, the community healthcare worker will be accessible to participants as she resides in their village within half a mile radius. Participants will know the house of the community healthcare worker and also have her contact number in case they need to communicate in-between weekly visits.

The health literacy intervention will last 3 months and includes a combination of the following four components:

1. Video tutorials: The health literacy video has been developed by the research team based on literature review, previous research experience and ground information of needs (online supplemental appendix 4). It will be divided into two different segments: (1) hygiene and sanitation, and (2) coronavirus awareness and prevention. Derived from the diffusion of innovations theory,<sup>25</sup> a screenplay showing interaction between a change agent (community healthcare worker) and an early adopter (disadvantaged woman in the community) will be used. The video will be communicated and reinforced through monthly repetition over the intervention period. Voice-over in the provincial language will be used, but the narrative will be evident through images and symbols. Therefore, even without voice-over the audience will be able to understand the messages being communicated.
2. One-on-one training for improving awareness and practices: Weekly one-on-one meetings will provide a forum for one-on-one communication between the community healthcare worker and the female client. It will offer opportunities for the community healthcare worker to discuss health generally, hygiene and sanitation, and coronavirus prevention and awareness in theory and practice. It will also provide the opportunity for women to share their challenges and to seek guidance on improvement, adoption and challenges related to health awareness and behaviour. The women will also be able to consult with healthcare practitioners, including female doctors and pharmacists via the smartphone.
3. Group training: Monthly group meetings will be an opportunity for community healthcare workers to collectively interact with their respective five intervention participants and discuss the interpretation of the health literacy video and individual meetings. The virtual group meeting will provide a platform for participants to share their challenges and gains to provide collective support and reinforcement, as well as the opportunity for information sharing. Group forums also have the benefit of encouraging questions and answers that individuals may not be able to address or voice in one-on-one sessions. Training content guidelines for the community healthcare workers for the one-on-one weekly and monthly group meetings for hygiene and sanitation and coronavirus awareness and prevention can be found in online supplemental appendix 5 and 6, respectively.
4. One-on-one training for a self-management chart: Separate weekly meetings with each participant will be held for training of a self-management chart (online supplemental appendix 7). This chart will be tailor made for each participant based on the information from baseline survey and their current health challenges and sociodemographic characteristics. It will be filled and updated weekly by the participants during the intervention period to help them track improvement in health practices, health behaviour and lifestyle



change related to hygiene, sanitation and preventive behaviour related to the coronavirus. For women who cannot type or write, this self-management chart will have the option of recording information through symbols.

### Development and piloting of the tools

The principal and coinvestigators have developed the tools for this study, including the surveys and the intervention. For strengthening validity and finalisation of the tools, two stages will be adopted after the recruitment of the community healthcare workers. At the first stage, focus group discussions with community healthcare workers in different provinces will be conducted to gain more information about their experiences with regard to women in their community and their challenges with regard to interaction, communication and service delivery. Additionally, the surveys and the intervention plans will be shared with the community healthcare workers in order to gain their feedback and recommendations for additions or deletion. At the second stage, after incorporation of feedback from community healthcare workers, a pilot test with 15 female participants will be conducted over a 2-week period. Participants for the pilot will be recruiting from the existing network of the community healthcare workers and will be chosen based on the selection criteria of the study. We will share the surveys (baseline survey and pretest survey questions) and the plans for the intervention with participants of the pilot study and ask them to provide feedback. The objective of the pilot will be to gain feedback about the ease of understanding the surveys and refinement of intervention material. Pilot study participants will not be included in the intervention later.

The surveys and intervention material have been developed in English and Urdu (the national language) and we will also be translating them in the provincial languages. The translation from Urdu to provincial languages (Baluchi for Baluchistan; Pashto for KPK; Punjabi for Punjab; and Sindhi for Sindh) will be done by experts in each language accompanied by four community healthcare workers from each province, fluent in Urdu and the respective provincial language. The translation will be done using the forward-backward method,<sup>26</sup> and will be double-checked by other language experts solicited for assistance after the internal team members have completed translations.

### Data collection

This study will be collecting self-reported data for the baseline survey, pretest survey and post-test survey. Data collection will employ an online-based approach. The digital format for survey data collection and intervention delivery has the advantage of enabling intervention deliverers and participants to answer/question/learn conveniently at their own preferred time, within their homes and at their own and family's convenience. We will be using the licensed software ClickMedix for recording and

storage of our survey data, sharing of videos, intervention delivery and video calls with healthcare specialists. This is a recommended software for health services and assures data security by keeping patient data confidential and secure.<sup>27</sup> Every user will have a separate login and password, and no user will be able to access an alternative account other than their own. All data and communication between community healthcare workers and female study participants will be recorded on ClickMedix and transferred to the principal investigator for permanent storage, record keeping and data analysis. Only the principal investigator will have access to the complete data on ClickMedix. Additionally, we will be ensuring privacy for women by ensuring that all meetings and trainings take place in either (1) a private space in participant's home, (2) a private space in community healthcare workers' home, or (3) the veranda or house garden of participant. Headphones will be used by community healthcare workers and participants when speaking to a healthcare specialist. Participants will not be provided any incentive to participate in this study. However, we believe the following elements will support retention of participants in the study: (1) health benefits for participants and their family, (2) familiarity, trust and cultural sensitivity of female community healthcare providers delivering intervention, and (3) frequency of contact.

### Data analysis

Data will be collected electronically on smartphones of community healthcare workers. Analysis will be conducted using SPSS version 25 after data cleaning prior to the analysis and analysing non-responders. As data collectors or female clients cannot be blinded, we will be ensuring that data analysis and outcomes being measured are as objective as possible by blinding the first data analyst. This will ensure that bias is avoided during the statistical analysis of the intervention results. The data analysis will be completed once by the blinded data analyst and then repeated by a second person to confirm validity. Furthermore, a third data analyst will be involved in checking and ensuring data management and result interpretation.

Data regarding refusal and dropout will be reported according to Consolidated Standards of Reporting Trials guidelines.<sup>28</sup> Descriptive statistics will be used to report baseline survey data with regard to health status of study participants. Associations between sociodemographic characteristics of women and broad health challenges of infectious disease, chronic disease, multimorbidity and mental health will be presented using binomial multivariate regression models. With regard to pre- and post-test results for the intervention,  $\chi^2$  test, means, SDs and analysis of variance will be used to present the differences between the intervention and control groups and to compare outcomes and change in health behaviour. In addition, multivariate logistic regression will be used to present ORs and 95% CIs to show the impact of the intervention through reporting higher likelihood of an improvement in health literacy between the intervention

and control groups. Levels of significance will be reported at  $p < 0.05$ .

### Data audit

Data analysis will be conducted by the principal and coinvestigator team. It will not involve the funders of this project. The data will be audited by independent senior scholars comprising the Office of Research, Innovation and Commercialization at Forman Christian College University. A weekly progress report will be provided to the auditors to help them monitor the project and provide feedback.

### Data storage and sharing

All data of the research project, the master file for survey data collection results and intervention results will be available in Excel files and SPSS. This data will be stored in the repository of the Forman Christian College University. Hard copies of all data collection (surveys and notes), unblended data and contractual agreements will be held securely by the principal investigator.

### Patient and public involvement

This study includes the view of the people involved in the research (disadvantaged women of reproductive age as well as community healthcare workers) at an early stage in the pilot testing. This offers the opportunity of rephrasing or including further questions in the questionnaire.

### Dissemination

A website will be developed for sharing aggregated data and sharing findings. Workshops will be held with health sector and stakeholders to share recommendations for policy improvements. Furthermore, we aim to disseminate the findings of our study via publication in an international peer-reviewed journal and through conference proceedings. The plans for future research include: (1) repeat nationwide cross-sectional data collection and longitudinal systematic data collection for women's health to a wider sample, (2) strengthening of partnership with government for team building between female community healthcare workers and other health workers for primary healthcare support of women, such as health social workers, and (3) including further digital health literacy interventions related to maternal and child health, nutrition and food security, and mental health counselling and therapy.

## DISCUSSION

Health literacy of women is a major problem in Pakistan and other LMICs due to low literacy generally, lack of inclusion in the general education curriculum and greater seclusion in the home.<sup>29</sup> Ironically, it is the women who are responsible for their own and their families' health overall and preventive behaviour for infection control. Luckily, health literacy for women from LMICs is gaining attention as it empowers poor and semiliterate women for informed decision-making and improved health

behaviour.<sup>30</sup> Non-digital health literacy interventions in LMICs have been successful in providing women of reproductive years support for family planning,<sup>31</sup> menstrual health,<sup>32</sup> child health<sup>33</sup> and mental health.<sup>34</sup> Improved health literacy in disadvantaged populations has been linked to improved health status, greater adherence to medication, better health recovery and decrease in hospitalisation.<sup>33</sup> At the macrolevel, health literacy interventions can improve maternal and child health indicators and decrease the health burden for LMIC nations, which are already resource short and facing greater infectious disease burden.<sup>35</sup>

The digitisation of health services has been identified by the WHO as a contemporary global strategy to improve health.<sup>36</sup> With the onslaught of the pandemic and the need for physical distancing, access to health information and health services through mobiles and internet assumes greater significance. The additional need of the hour in LMICs is to provide digital health literacy interventions related to hygiene and coronavirus management to women of reproductive years to secure maternal, child and family health. Technology-based health literacy interventions, using digital devices and the internet, have been successful in LMICs,<sup>37</sup> especially when efforts have been made to develop use of easy reading materials and use of numbers, pictures and colour.<sup>38 39</sup> However, there have been difficulties with regard to the overall assessment of RCT impact due to differences in methods and research design, and measurement of outcomes in cities or provinces rather than at national level.<sup>40–42</sup>

In Pakistan, digital health interventions have so far focused on short message service for heart patients,<sup>43</sup> mobile services for patients with diabetes<sup>44</sup> and provision of a mobile app to access online consultancy from a doctor.<sup>45</sup> Other interventions have targeted to empower healthcare providers and record and manage patient information.<sup>46 47</sup> So far, interventions have been targeting populations who already own and use a mobile phone or smartphone and have knowledge about downloading health-related apps.<sup>48</sup> Another limitation is that interventions so far in the country have targeted general health and non-communicable diseases, and there have been no efforts to improve literacy for hygiene, sanitation and coronavirus management in disadvantaged women.<sup>49</sup> There have also been few interventions involving community-based intervention and female community healthcare workers in Pakistan.<sup>50</sup> Difficulties in conducting digital interventions in LMICs include: (1) high costs and shortage of national and international funding for such projects, (2) problems related to internet access in remote areas, (3) barriers in communicating with semiliterate populations, and (4) lack of cultural acceptability with regard to the use of technology, especially for women.<sup>51</sup>

This protocol describes the methods for an RCT which aims at investigating the effects of a digital health literacy intervention to empower female clients and healthcare providers of the community. This study will make an important contribution by improving participants'



understanding with respect to hygiene, sanitation and coronavirus prevention, and will also present comparative results between a control group and intervention group to highlight the impact of the intervention delivery. We believe this study will change the landscape of primary healthcare delivery services by digitalising services and improving service delivery standards of community healthcare workers.<sup>52</sup> Empowering disadvantaged women with health access digitally will also open avenues for women in accessing future opportunities related to communication, employment and small business development. Digital health literacy in Pakistan, during the coronavirus pandemic, would also contribute to improvements in patient safety, referral for other health and social needs through community healthcare workers, and ultimately enhance the socioeconomic potential of the country. It is hoped that this study and further research can plan more comprehensive literacy and awareness interventions in primary healthcare settings for disadvantaged women related to other maternal and child health areas, nutrition and food security, chronic disease and multimorbidity management, and mental health counselling.

#### Author affiliations

<sup>1</sup>Department of Sociology, Forman Christian College University, Lahore, Pakistan

<sup>2</sup>School of Pharmacy, University College London, London, UK

<sup>3</sup>Department of Mass Communications, Forman Christian College University, Lahore, Pakistan

<sup>4</sup>Department of Business, Forman Christian College University, Lahore, Pakistan

<sup>5</sup>Institute of Public Health, Charité–Universitätsmedizin Berlin, Berlin, Germany

<sup>6</sup>Institute of Gerontological Health Services and Nursing Research, Ravensburg-Weingarten University of Applied Sciences, Weingarten, Germany

**Twitter** Sara Rizvi Jafree @JafreeRizvi

**Acknowledgements** We would like to thank Professors Dr Sikandar Hayat and Dr Kauser Malik for their support and guidance during the development of this project. Sincerest thanks is also due to Professor Syeda Khadija Burhan and Dr Amna Khawar for assistance in review of the content developed for the health literacy intervention. We acknowledge support from the German Research Foundation (DFG) and the Open Access Publication Fund of Charité–Universitätsmedizin Berlin.

**Contributors** SRJ planned and developed the trial intervention. FF and AM provided expertise with the research design. NB helped to gain funds for the project. SRJ, AM and FT have developed the material for data collection and health literacy intervention. SRJ drafted the protocol. FF and AM revised it critically for important intellectual content. All authors approved the final version of this manuscript.

**Funding** This project was funded by doctHERS, in partnership with University of Health Sciences (UHS), Punjab Population Innovation Fund (PIIF), Women Chamber of Commerce and Industry (WCCI) and Rural Support Programmes Network (RSPN), under their joint agreement to provide maternal, child, health and family planning services via telemedicine to underprivileged women of Pakistan. The contact point for doctHERS is asher@docthers.com. The funds will be used for the following expenses: digital assets (smartphone, Wi-Fi and video development), stipend for two research assistants and stipend for community healthcare workers who will be collecting the data and delivering the intervention. The principal and coinvestigators are not receiving a salary for this project. The funding body will not be involved in study design, data management or interpretation of data.

**Competing interests** None declared.

**Patient consent for publication** Not required.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Supplemental material** This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those

of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

**Open access** This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

#### ORCID iD

Florian Fischer <http://orcid.org/0000-0002-4388-1245>

#### REFERENCES

- MacMahon S. *Multimorbidity: a priority for global health research*. London, UK: The Academy of Medical Sciences, 2018.
- Singh K, Patel SA, Biswas S, et al. Multimorbidity in South Asian adults: prevalence, risk factors and mortality. *J Public Health* 2019;41:80–9.
- Nishtar S. *Choked pipes: reforming Pakistan's mixed health system*. Karachi: Oxford University Press Karachi, 2010.
- Pati S, Swain S, Hussain MA, et al. Prevalence and outcomes of multimorbidity in South Asia: a systematic review. *BMJ Open* 2015;5:e007235.
- Fund IM. *World economic outlook database – October 2019*. Washington: International Monetary Fund, 2019.
- Mumtaz K. Gender and poverty in Pakistan. *Development* 2007;50:149–53.
- Nasrullah M, Bhatti JA. Gender inequalities and poor health outcomes in Pakistan: a need of priority for the National health research agenda. *J Coll Physicians Surg Pak* 2012;22:273–4.
- Barnett K, Mercer SW, Norbury M, et al. Epidemiology of multimorbidity and implications for health care, research, and medical education: a cross-sectional study. *Lancet* 2012;380:37–43.
- Begum Sadaquat M, Sheikh Qurra-tul-ain Ali. Employment situation of women in Pakistan. *Int J Soc Econ* 2011;38:98–113.
- Beeson JG, Homer CS, Morgan C, et al. *Multiple morbidities in pregnancy: Time for research, innovation, and action*. San Francisco, CA, USA: Public Library of Science, 2018.
- Aubert CE, Fankhauser N, Marques-Vidal P, et al. Patterns of multimorbidity in internal medicine patients in Swiss university hospitals: a multicentre cohort study. *Swiss Med Wkly* 2019;149:w20094.
- Abdullah MA, Mukhtar F, Wazir S. The health workforce crisis in Pakistan: a critical review and the way forward. *World Health Popul* 2014;15:4–12.
- Qiao J. What are the risks of COVID-19 infection in pregnant women? *Lancet* 2020;395:760–2.
- Schwartz DA. An analysis of 38 pregnant women with COVID-19, their newborn infants, and maternal-fetal transmission of SARS-CoV-2: maternal coronavirus infections and pregnancy outcomes. *Arch Pathol Lab Med* 2020;144:799–805.
- Contant Éric, Loignon C, Bouhali T, et al. A multidisciplinary self-management intervention among patients with multimorbidity and the impact of socioeconomic factors on results. *BMC Fam Pract* 2019;20:53.
- Hunt A, Samman E. *Women's economic empowerment: Navigating enablers and constraints*. J UN High Level Panel on Women's Economic Empowerment background paper. London: Overseas Development Institute, 2016.
- Yamane T. *Statistics: an introductory analysis*. New York: Harper & Row, 1973.
- Cho C. Random number generator with random sampling, 2011. Google patents. Available: <https://patents.google.com/patent/US6324558B1/en> [Accessed 26.02.2021].
- Jalal S. The lady health worker program in Pakistan—a commentary. *Eur J Public Health* 2011;21:143–4.
- Douthwaite M, Ward P. Increasing contraceptive use in rural Pakistan: an evaluation of the lady health worker programme. *Health Policy Plan* 2005;20:117–23.
- Khan IA. Public sector institutions, politics and outsourcing: reforming the provision of primary healthcare in Punjab, Pakistan. *Journal of International Development* 2010;22:424–40.



- 22 Pati S, Hussain MA, Swain S, *et al.* Development and validation of a questionnaire to assess multimorbidity in primary care: an Indian experience. *Biomed Res Int* 2016;2016:1–9.
- 23 Osborne RH, Elsworth GR, Whitfield K. The health education impact questionnaire (heiQ): an outcomes and evaluation measure for patient education and self-management interventions for people with chronic conditions. *Patient Educ Couns* 2007;66:192–201.
- 24 Afzal MS, Khan A, Qureshi UUR. Community-based assessment of knowledge, attitude, practices and risk factors regarding COVID-19 among Pakistanis residents during a recent outbreak: a cross-sectional survey. *J Community Health* 2020;1–11.
- 25 Rogers EM. *Diffusion of innovations*. New York: Simon and Schuster, 2010.
- 26 Maneesriwongul W, Dixon JK. Instrument translation process: a methods review. *J Adv Nurs* 2004;48:175–86.
- 27 Ho B, Lee M, Armstrong AW. Evaluation criteria for mobile tele dermatology applications and comparison of major mobile tele dermatology applications. *Telemed J E Health* 2013;19:678–82.
- 28 Altman DG, Schulz KF, Moher D, *et al.* The revised consort statement for reporting randomized trials: explanation and elaboration. *Ann Intern Med* 2001;134:663–94.
- 29 Das S, Mia MN, Hanifi SMA, *et al.* Health literacy in a community with low levels of education: findings from Chakaria, a rural area of Bangladesh. *BMC Public Health* 2017;17:1–10.
- 30 Vaz NFM. Mobile health literacy to improve health outcomes in low-middle income countries, in health care delivery and clinical science: concepts, methodologies, tools, and applications. *IGI Global* 2018:1398–411.
- 31 Kilfoyle KA, Vitko M, O'Connor R, *et al.* Health literacy and women's reproductive health: a systematic review. *J Womens Health* 2016;25:1237–55.
- 32 Kansime C, Hytti L, Nalugya R, *et al.* Menstrual health intervention and school attendance in Uganda (MENISCUS-2): a pilot intervention study. *BMJ Open* 2020;10:e031182.
- 33 DeWalt DA, Hink A. Health literacy and child health outcomes: a systematic review of the literature. *Pediatrics* 2009;124 Suppl 3:S265–74.
- 34 Jorm AF. Mental health literacy: empowering the community to take action for better mental health. *Am Psychol* 2012;67:231–43.
- 35 Peters DH, Garg A, Bloom G, *et al.* Poverty and access to health care in developing countries. *Ann N Y Acad Sci* 2008;1136:161–71.
- 36 Holeman I, Cookson TP, Pagliari C. Digital technology for health sector governance in low and middle income countries: a scoping review. *J Glob Health* 2016;6:020408.
- 37 Meherali S, Punjani NS, Mevawala A. Health literacy interventions to improve health outcomes in low- and middle-income countries. *Health Lit Res Pract* 2020;4:e251–66.
- 38 Kripalani S, Weiss BD. Teaching about health literacy and clear communication. *J Gen Intern Med* 2006;21:888–90.
- 39 Tortajada S, Giménez-Campos MS, Villar-López J, *et al.* Case management for patients with complex multimorbidity: development and validation of a coordinated intervention between primary and hospital care. *Int J Integr Care* 2017;17:4.
- 40 Ahmed J, Shaikh BT. The state of affairs at primary health care facilities in Pakistan: where is the state's stewardship? *East Mediterr Health J* 2011;17:619–23.
- 41 Loevinsohn B, Haq IU, Couffinhal A, *et al.* Contracting-in management to strengthen publicly financed primary health services—the experience of Punjab, Pakistan. *Health Policy* 2009;91:17–23.
- 42 Mumtaz Z, Levay A, Bhatti A, *et al.* Good on paper: the gap between programme theory and real-world context in Pakistan's community midwife programme. *BJOG* 2015;122:249–58.
- 43 Kamal AK, Shaikh Q, Pasha O, *et al.* A randomized controlled behavioral intervention trial to improve medication adherence in adult stroke patients with prescription tailored Short Messaging Service (SMS)-SMS4Stroke study. *BMC Neurol* 2015;15:1–11.
- 44 Hashmi NR, Khan SA. Interventional study to improve diabetic guidelines adherence using mobile health (m-Health) technology in Lahore, Pakistan. *BMJ Open* 2018;8:e020094.
- 45 Ullah N. A telemedicine network model for health applications in Pakistan: current status and future prospects. *JDCTA* 2009;3:149–55.
- 46 Hall CS, Fottrell E, Wilkinson S, *et al.* Assessing the impact of mHealth interventions in low- and middle-income countries—what has been shown to work? *Glob Health Action* 2014;7:25606.
- 47 Zaidi S, Shaikh SA, Sayani S, *et al.* Operability, acceptability, and usefulness of a mobile APP to track routine immunization performance in rural Pakistan: interview study among vaccinators and key informants. *JMIR Mhealth Uhealth* 2020;8:e16081.
- 48 Jacobs RJ, Lou JQ, Ownby RL, *et al.* A systematic review of eHealth interventions to improve health literacy. *Health Informatics J* 2016;22:81–98.
- 49 Kazi AM, Qazi SA, Ahsan N, *et al.* Current challenges of digital health interventions in Pakistan: mixed methods analysis. *J Med Internet Res* 2020;22:e21691.
- 50 Bhutta ZA, Ali S, Cousens S, *et al.* Alma-Ata: rebirth and revision 6 interventions to address maternal, newborn, and child survival: what difference can integrated primary health care strategies make? *Lancet* 2008;372:972–89.
- 51 Mbuagbaw L, Thabane L, Ongolo-Zogo P, *et al.* The challenges and opportunities of conducting a clinical trial in a low resource setting: the case of the Cameroon mobile phone SMS (camps) trial, an investigator initiated trial. *Trials* 2011;12:1–7.
- 52 Sultan F, Khan A. Infectious diseases in Pakistan: a clear and present danger. *Lancet* 2013;381:2138–40.