Original Article

Ramadan fasting research during the COVID-19 pandemic in the United Kingdom: recruitment challenges

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Background: Many Muslims in the UK perform a dawn to dusk fasting, with no food and water, for 29–30 days during the month of Ramadan. Adults and some children, with type 2 diabetes (T2D), also engage in fasting often without medical guidance. The potential benefits or harms associated with this have not been well investigated. This report discusses and reflects the experience of developing questionnaire-based studies and the challenges faced in engaging Ramadan fasting (RF) children and young adults in this research during the COVID-19 pandemic in the UK.

Methods: SoGoSurvey software was used to design retrospective and prospective questionnaires, which gathered information on medical history, lifestyle and COVID-19 pandemic-related impacts. The questionnaires were sent to healthy people and patients with T2D aged from 12 to 80 years old, who planned to fast during Ramadan for a minimum of 10 days. The participants were recruited from several communities and medical centres in the UK. Participants were contacted by phone and email.

Results: The response rate for the retrospective questionnaire (27.5%), which included people with and without T2D, was lower than expected even though it was close to the average of the current online surveys responses at about 30%. The majority of the respondents were from the "other ethnicities group" at 65.4%. Moreover, the response rate for the prospective study among only patients with T2D was at 22.5%. The youngest people with T2D who fasted during Ramadan were 14 years old.

Conclusions: The low percentage of completion of the questionnaires may be due to COVID-19 pandemic restrictions. Furthermore, it is known that participation in research is low amongst ethnic minority population in the UK. Creating greater awareness about the importance of participation in research studies within ethnic minority groups in the UK is needed. Face-to-face completion of questionnaires with the researcher could be the most effective approach for engaging 12 to 16 years old children in research.

Keywords: Type 2 diabetes (T2D); Ramadan fasting (RF); children; young adults; COVID-19

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Introduction

Research in children and young adults has been conducted over decades and proved to be associated with some challenges, compared to the studies among adults. Several institutions provided certain guidance to follow by taking all the related ethical issues into considerations (1-3). These include the written consents and assents, which need to be clear in a lay understandable language and provided to the interested participants before the start of the study in a reasonable time (1,4). The researchers must make sure that the parents understand the inconveniences and the risks associated with any research study. Furthermore, the children and the young adults must show willingness

to participate (3,4). All these important issues, although complicated and challenging, must be considered for carrying out research in an ethical manner. COVID-19 pandemic restrictions have made this process much harder for the researchers by having to find alternative tools to conduct research under a safe environment (5,6). As a result, remote communications with the interested participants have become more popular during the outbreak period of COVID-19 (7,8).

For instance, using online survey tool software such as SoGoSurvey and Survey Monkey could be beneficial in terms of revealing people's views and opinions (9,10). It has been recommended as one of the alternative research approaches during the pandemic (11,12). This may also provide valuable information on how several patients with chronic illnesses, such as diabetes, could be influenced by the unprecedented circumstances of COVID-19 (11), including the impacts on their medical conditions, mental health, and access to medical services. Moreover, respondents can complete the survey at their convenience and avoid face-to-face contact with the research team. In addition, it has been reported that questionnaires are flexible and cost effective in terms of providing/delivering them to respondents and data analysis (12,13). However, questionnaire-based studies are associated with some obstacles particularly when it comes to the sampling and the response rate (14). Likewise, survey research collects self-reported data, and this may consequently have an impact on the accuracy of the answers and the study quality in general (14). Therefore, any data obtained will need to be confirmed using other study designs in the future.

Millions of Muslims observed Ramadan fasting (RF) during 2020, and this was in the midst of the COVID-19 pandemic. Certain ethnic groups in the UK and world-wide, including Muslims, were disproportionately affected by COVID-19 and some were concerned that fasting could bring additional health risks (15,16). However, it has been reported that RF during the COVID-19 pandemic is not a cause for concern for healthy people who adopt a balanced diet, drink plenty of fluids and engage in regular physical activities (17). Another study reported that Ramadan was not associated with an increase in COVID-19 infection risk (18). However, fasting during the global outbreak could lead to serious complications among high-risk patients such as patients with type 2 diabetes (T2D). The inability to carry out any physical activity due to COVID-19 quarantine has been identified as a serious health issue and some have suggested types of physical activities that people can perform at home (19,20). Therefore, questionnaire-based studies could provide an overview on whether people were physically active or not during the month of Ramadan. Furthermore, it has been shown that RF has a favourable effect by helping to overcome stress and a positive impact on alertness (21,22). Therefore, these impacts could help some Muslims who have experienced mild stress during the COVID-19 outbreak, such as anxiety due to social isolation.

According to Diabetes UK, children with diabetes can get COVID-19 infection, however the risk of developing severe illness is extremely rare (*Updates: Coronavirus and diabetes. 2020*). Yet, these patients are still vulnerable to COVID-19 infection and caution should be exercised and close health care observations are highly recommended, in particular with patients who have uncontrolled blood glucose and secondary complication of diabetes (23). Data from several studies suggest that RF is associated with favourable effects on weight reduction and blood glucose control among adult patients with T2D (24-27). In addition, RF is associated with a significant improvement in glucose biomarkers (28,29). However, evidence from other studies reported that RF might worsen the disease in some of these patients and lead to serious complications such as hypoglycaemia (30-32). Therefore, findings from the current literature are controversial and this could be related to the great variations in methods approaches and sample size (33). Moreover, Diabetes and Ramadan (DAR) International Alliance (https://daralliance.me/) community has provided a great support for these patients and for medical professionals by developing an updated practical guideline (34). This was based mainly on the expert opinions.

Thus, since people with T2D among children (around 12 years old) and young adults usually engage in fasting during the month of Ramadan with no medical observation, it is important to investigate how these patients are affected compared to healthy individuals. Such knowledge will be valuable for preventing harmful effects during a future pandemic. Consequently, this study will provide valuable information for the health care providers and the entire population. In this context, the authors of this paper developed two studies; the first was a retrospective questionnaire-based study to reflect the impacts of COVID-19 pandemic on people with and without T2D during Ramadan 2020, and the second was a prospective study aimed to investigate the impacts of fasting during Ramadan 2021 on T2D. The latter was conducted by administering two questionnaires before and after the month of Ramadan. This research paper will discuss the

challenges faced in carrying out these two studies during the pandemic period, in terms of obtaining the ethical approvals, recruitment and communication with the participants. We present the following article in accordance with the SURGE reporting checklist (available at https://jphe.amegroups.com/article/view/10.21037/jphe-22-18/rc).

Methods

Two ongoing studies have been designed and developed based on online questionnaires. SoGoSurvey software was used to design the questionnaires (9). The participants information sheets were uploaded to the software and provided in links where the respondents can download and read at a convenient time. Even though the same tool was used for the two studies, the design for both studies was different.

First study: *"Effects of Ramadan Fasting during COVID-19 pandemic on people with and without Type 2 Diabetes"*

This study was designed as a retrospective survey-based study to obtain views/concerns on the effects of COVID-19 on several lifestyle aspects, such as diet, physical activities and sleeping patterns during Ramadan 2020 on children, young adults and adults. The questionnaire has been adapted from European Prospective Investigation into Cancer (EPIC)-Norfolk food frequency questionnaire (FFQ) (35). This EPIC-Norfolk FFQ comes along with Open Government Licence for public sector information, which will allow the copying, use, publishing and transmission of information (35). It has been modified and converted to an online version. The questionnaire then has been validated by distributing it among different age groups and they have been asked to provide an evaluation/feedback, such as the time taken to complete the survey and the clarity of the questions. All the feedback had been taken into consideration to enhance it much more and avoid any confusion that might occur. The target age group for this study was from 12 to 80 years including healthy individuals and people with T2D. Healthy individuals have been defined as people who do not have diabetes and not take any medications.

All ethnic groups from the UK who have chosen to fast for a minimum of 10 days during Ramadan 2020 were included. People who have mental disabilities and people who do not know/understand the English language were excluded. The interested participants (healthy and patients with T2D) were recruited from various communities in the UK, including mosques and De Montfort University. The URL links of the survey were distributed using several ways including social media groups/communities (Facebook, WhatsApp and Twitter), emails and asking the participants to share the links with their friends or family members (snowball technique). The participants were provided with two links to access; one for children aged from 12 to 15 years old and the other link was for people aged from 16 to 80 years old. Reminders were sent three times.

The questionnaire was divided into four sections:

(I) Information about you: age, gender, employment status (for people aged 16+ years old), ethnicity and physical measurements [blood pressure (BP), weight and height].

(II) RF and COVID-19 pandemic: in this section the participants were required to answer some questions related to COVID-19 and fasting.

(III) Health and medical history: this section was exclusively intended for patients with T2D in order to provide background on their medical history (in relation to diabetes) and the level of the blood glucose control during quarantine situations.

(IV) Lifestyle-related information: this section was designed for both, healthy individuals and patients with T2D. This had covered all the questions related to diet intake, sleep duration/time and physical activity. Also, some questions related to COVID-19 were added to explore the impact of COVID-19 on other aspects of lifestyle.

No personal information was collected (names, addresses). The survey was self-administered, and the participants were instructed that they can complete all the survey sections within 15 to 20 minutes at their convenient time. Although the questionnaire has been designed in lay language, children who are at 12 can complete it with their parents in order to help to answer all the questions as precisely as possible. The participants were required to do the following:

- Read the participants information sheets carefully;
- If they are interested to participate, they have to agree on the consent statements provided;
- Compete all the questionnaire sections.

This survey-based study was aimed to collect 300 responses. This sample size was established by reviewing the current literature on the best recommended way for a survey-based research study (36,37). The respondents were given the opportunity to complete the questionnaire over a reasonable time and were encouraged to complete it as soon

as possible. The ethical approval for this study was obtained via De Montfort University, Faculty of Health and Life Sciences Research Ethics Committee (FREC).

Second study: *"Effects of Ramadan Fasting on Children and Young Adults with Type 2 Diabetes"*

This study was designed as a prospective, observational, cross over, pilot study to examine the effects of RF on lifestyle aspects (physical activity, sleep, diet patterns) and blood glucose biomarkers in children and young adults with T2D. In addition, the impacts of COVID-19 pandemic on patients with diabetes was considered. Questionnaires were designed and adapted from the same source as explained above, in the first study. However, the questionnaires data of this study were measured at two points: 2 weeks before Ramadan 2021 and 2 weeks after Ramadan 2021. The target age group was from 12 to 24 years old (males and females) and who are diagnosed with T2D. All ethnic groups from the UK who have chosen to fast for a minimum of 10 days during the month of Ramadan were included. Participants who decided to withdraw from the study after completing only the questionnaire before the month of Ramadan were excluded. Furthermore, healthy individuals, people with mental disability, and none-English speakers were excluded.

The sample size was calculated using G*Power, which is a freely available software for sample size calculation and power analysis (38). According, the estimated total sample size was 34 (effect size: 0.5 and actual power: 0.80). Moreover, two sampling methods were followed; convenience sampling (Non-Probability Sampling Methods) and cluster sampling (Probability Sampling Methods). The interested participants were recruited from three diabetes centres in the UK. They were approached first by the clinical collaborators and then guided to contact the researcher who provided them all the information needed and guided them throughout the course of the study. Moreover, the participants were contacted mainly by telephone calls and emails. Reminders were sent three times for some participants. The questionnaires links were sent to the participants before and after the month of Ramadan within 2 weeks. One for children who are aged from 12 to 15 years old, and the other link was for people aged from 16 to 24 years old. The questionnaires were anonymised. Besides, the informed consent and assent were made clear that participation is always voluntary. All the participants information sheets have been uploaded to the online survey, where the respondents can download and read at their own time.

The questionnaire had four sections:

(I) Information about you: age, gender, employment status (for people aged 16 to 24 years old) and physical measurements.

(II) RF and COVID-19: in this section the participants were asked some questions related to COVID-19 and fasting.

(III) Health and medical history: this section asked for background on the patient's medical history (in relation to diabetes) and the level of the blood glucose control before and after the month of Ramadan.

(IV) Lifestyle-related information: this section covered all the questions related to dietary intake, sleep duration/time and physical activity. Also, some questions related to COVID-19 were added to explore the impact of COVID-19 on all aspects of lifestyle.

Further, the previously recorded blood glucose biomarkers for the relevant participants were retrieved from patients' medical records over a couple of years. The patients were asked to consent this to be done by the researcher in collaboration with the clinical consultants. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The ethical approval for this study was obtained from the FREC and the Health Research Authority (HRA) UK. For this study, participants were received two vouchers; £10 before and £10 after Ramadan to compensate their time and inconvenience.

Data handling and statistical tests

Data were exported from the SoGoSurvey software to the Statistical Package for the Social Sciences (SPSS), version 26 (IBM Corporation, Armonk, NY, USA) for the analysis. In SPSS the data were organised, cleaned, and coded. The survey questions were divided into three types including, category variables, ordinal variables, and continuous variables. The distribution of the continuous variables were examined using visual inspection and statistical test. Shapiro & Wilk's test ($P<0.05$) and histogram, Q-Q plot and Box plot. Descriptive statistics analysis was conducted, mean ± standard deviation (SD) was used for continuous variables which are normally distributed, and the median and inter quartile range (IGR) was used for the skewed data. Percentages and counts were used for the categorical variables. The statistical significance was appointed at $P<0.05$ (two-tailed).

Table 1 Demographic characteristics of participants who fasted during Ramadan 2020 (N=81)

Characteristics	N	%
Gender		
Male	32	39.5
Female	49	60.5
Age in groups, years old		
12–15	11	13.6
16–24	11	13.6
25–80	59	72.8
Race/ethnicity		
White	1	1.2
Asian Bangladeshi	5	6.2
Asian Pakistani	7	8.6
Asian Indian	7	8.6
Any other Asian background	2	2.5
Black African	3	3.7
Black Caribbean	0	0
Any other Black/African/Caribbean background	1	1.2
Mixed/multiple ethnic groups	2	2.5
Other ethnic group	53	65.4
T2D		
Yes	4	5.0
No	76	95.0

T2D, type 2 diabetes.

Table 2 Demographic characteristics of participants (patients with T2D) who fasted during Ramadan 2021 (N=9)

Characteristics	N	%
Gender		
Male	2	22.2
Female	7	77.8
Age, years old		
14	2	22.2
15	1	11.1
17	2	22.2
18	3	33.3
22	1	11.1

T2D, type 2 diabetes.

Results

The initial descriptive data obtained have been summarised including the demographic information and the response rate for each study. This was later calculated manually based on a standard response rate (39).

"Effects of Ramadan Fasting during COVID-19 pandemic on people with and without Type 2 Diabetes"

Three hundred people from different age groups were recruited, but only 81 individuals completed the retrospective questionnaire. As a result, the response rate for the first study was 27%. The respondents were grouped based on gender and age groups and the percentage of each group were calculated (*Table 1*). More than a half of the total participants were females (60.5%) and the median (IQR) age was 33 years old (21), while males were at 39.5% and the median (IQR) age was 40 years old (17). The vast majority of the respondents (95%) were healthy individuals (*Table 1*). Moreover, 72.8% of the participants were young adults and adults ranged from 25 to 80 years old.

"Effects of Ramadan Fasting on Children and Young Adults with Type 2 Diabetes"

A total of 40 patients with T2D were recruited for this study, but only nine patients responded and completed both questionnaires, before and after the month of Ramadan. As a consequence, the response rate was at 22.5%. As shown on *Table 2*, the vast majority of participants were females (77.8%) and the mean age was 17±3 years old, while the mean age for males was 16±3 years old (22.2%). The youngest patients who fasted during Ramadan, including a male and a female, were 14 years old. They were able to fast for 10 to 15 days. All the data collected from the questionnaires during Ramadan 2021 have been analysed and compared with the data collected over the previous years including 2020, 2019, and 2018. However, the data analysis is ongoing, and it will be published in due course.

Discussion

In the present report, the authors have identified the challenges faced during conducting two online

questionnaire-based studies among children, young adult and adults during the COVID-19 pandemic. Pursuing research is fundamental under any unprecedented circumstances including global pandemics such as the COVID-19 pandemic as it will provide valuable information for health promotion and disease prevention. People with health issues such as diabetes always need support and updated guides to prevent the progression of the disease and development of any serious complications. This was agreed by other research groups (11,12). It has been concluded that conducting research during the pandemic is challenging, however the feasibility and the technology available could help the researchers to adapt and develop new methods for data collection. Consequently, this will help researchers to provide solutions to people who are affected by the pandemic conditions in the future.

One of the most difficult challenges faced during this research was the amendments applied to cope with government rules and restrictions due to the pandemic. For instance, the ethical approval of the second study was already obtained from the HRA UK before the start of the pandemic and this was based on face-to-face communications with the participants. Therefore, as a result of COVID-19, substantial changes had to be made. The research team had several meetings to discuss and decide the best approach/alternative methods to redesign the study taking all the ethical issues into consideration. The questionnaires were changed to online versions and the communications with the participants were changed to be based on phone calls and emails. Thus, there was a great amount of pressure on the researcher to amend all the paperwork required and taking all the ethical issues into considerations. For example, the consent and the assent statements were developed electronically in a lay language suitable for the different age groups included. In addition, the HRA UK was facing great pressure in reviewing the other studies related to COVID-19 infection so delay in the response was expected at that time. For this reason, this study was postponed to the following year. Furthermore, the second study was conducted in three diabetes centres in the UK, and the study was set up in each centre according to the local regulations. Subsequently, the researcher made a monumental effort to provide all the updated documents needed for each site.

Several studies examined the feasibility and the quality of research based on online surveys (40-42). They have argued that this method facilitates the researchers to reach to many populations in an easy and cost-effective way (40-42). Moreover, it has been reported that online questionnaires can be completed by the participants in a short time (41). However, this was not observed in this research even though the questionnaires links were distributed via social media and emails to different communities. The participants were reminded many times to complete the questionnaires, and this was because reminders have been found to have a positive impact on the response rate (43). Taking a long time to complete the questionnaires could be related to the period of COVID-19 pandemic as the number of broad online questionnaires received by people has increased significantly (7). Furthermore, this research was studying the impacts of RF among ethnic minorities who traditionally are less willing to participate in research studies as reported (44). Thus, it could be argued that increasing the awareness on the importance of conducting research in ethnic minorities is essential as this may help in improving health care for these people. For instance, for Muslims this could take place in mosques where Imams (religious leaders) and community leaders can encourage people to participate and to be involved in the research process. Further, it has been noticed that a combination of data collection methods could increase the response rate among ethnic minorities (45).

To date, our study on the impacts of RF among children and young adults with T2D was the first study to evaluate the impacts of fasting on these patients taking the consequences of COVID-19 pandemic into consideration. Therefore, including children in the research was associated with some challenges involving ethical issues (assent form, clear statements, assessing the harms and risks). Similarly, this was reported in other research studies (46,47). Moreover, there was an effort to encourage the patients to complete the questionnaires required and within the time planned. The reminders were effective with some of the participants.

Even though the response rate in the first study (27%) was lower than expected, it was not far from the average of the response rates in the recent published research (48). It has been noticed that the response rates to surveys have been declining over the previous years. However, the lower response rate should not constrain researchers from conducting more studies as the lessons learnt may have an impact on improving the quality of the future studies. This could be overcome by reconducting the study using alternative methods such as completing questionnaires in person as it has been reported that face-to-face studies among children and young adults could be the best

approach to follow (49). Experiences from the current study are in good agreement with these statements.

Conclusions

Increasing the awareness of people about the importance of conducting research is key to improving health care. The low percentage of completion of the questionnaires in the current study may be due to COVID-19 pandemic restrictions. Evidence-based guidance is the best approach to tackle the progress of chronic disease among different age groups. Thus, continuous high-quality research is essential to provide the best practical guide and decrease the pressure on healthcare providers. Research challenges and reflecting researchers' experiences may help to develop the most possible, feasible and practical approaches. Therefore, the authors of this work have reached the following recommendations in relation to conducting online-based research among children and young adults when investigating the impacts of RF on patients with and without T2D:

(I) Planning is essential to adapt with any unprecedent circumstances that could be faced for any reason;
(II) Face-to-face completion of questionnaires with the researcher could be the most effective approach for engaging 12 to16 years old children in research. Availabilities of vaccines could make this more feasible. This research has provided evidence that children as young as 14 years old, with T2D, fast during the month of Ramadan;
(III) Expanding the recruitment period over months instead of weeks could increase the response rate;
(IV) Using media and frequent communities' meetings among ethnic minorities could give people an insight on the importance of the research studies;
(V) Frequent reminders have an effective impact on increasing the response rate of the online questionnaires;
(VI) Including more medical sites locally and internationally could have a great impact on increasing the enrolment in order to obtain robust data and statistics.

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The patients were asked to consent this to be done by the researcher in collaboration with the clinical consultants. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The ethical approval for this study was obtained from the FREC and the HRA UK.

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