Exploring the impact of COVID-19 on the willingness of older adults to participate in physiology research: views from past and potential volunteers

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Abstract

We explored the views of older (\geq 65 years) past and potential volunteers in regard to participating in physiology research during the COVID-19 pandemic. Using an online questionnaire and focus groups, we found that past volunteers (n=55) were more likely to take part in both acute (p<0.05) and chronic (p<0.05) physiology studies, compared to potential future volunteers (n=57). Both cohorts demonstrated a positive attitude towards volunteering during the COVID-19 pandemic, although concern was evident.

Novelty

 Volunteers demonstrated a positive attitude and also concern towards participating in physiology research during COVID-19

Keywords: ageing, COVID-19, physiology, research, recruitment, clinical trials

Introduction

The coronavirus disease (COVID-19) pandemic was announced in March 2020 (WHO 2020) and by June 2021 >174 million cases and >3.7 million deaths were recorded across 191 countries (WHO 2021). The risk of serious illness or death from COVID-19 increases with chronological ageing, thus posing a significant threat to the health and well-being of older adults (The Physiological Society 2020).

COVID-19 continues to cause significant disruption to human clinical trials, just as previous pandemics have (Gobat et al. 2018; Padala et al. 2020b), which is a major cause for concern since these trials are crucial to understanding the mechanisms of, and countermeasures against, age-related physiological decline (e.g., sarcopenia) (Deane et al. 2020). Indeed, the virulence of COVID-19, in part due to its asymptomatic transmission (Wiersinga et al. 2020), has led to the implementation of national lockdowns and the subsequent pausing of certain clinical and physiological research programmes. The initial halt to human physiology trials at the onset of the pandemic required principal investigators to consider the risk to volunteers, local/national guidance and ethical considerations, before deciding on the appropriate course of action and the possible re-start of such trials (Padala et al. 2020a; Padala et al. 2020b). Yet, despite the fact that such studies ultimately depend on the willingness of volunteers to participate, their views and opinions are rarely sought and considered (Padala et al. 2020a; Padala et al. 2020b).

As such, it is imperative to understand the factors that shape volunteer willingness to participate in research during unprecedented times, which will ultimately aid the continuation of research during the current COVID-19 pandemic and related future challenges such as severe influenza/viral pandemics. Therefore, the aims of this work were three-fold: i) to explore the views of "past" (i.e., those who *had* previously taken part in research with the current research

team) and "potential" (i.e., those who *had not* previously taken part in research with the current research team) older (≥65 years) volunteers in regard to participating in physiology research during the COVID-19 pandemic, using an online questionnaire, ii) to explore these views further using online focus groups, and iii) to provide practical recommendations to facilitate the successful recruitment of older adults during the current COVID-19 pandemic and future related challenges. Of note, physiology research herein refers to human clinical trials testing the efficacy of nutritional and/or exercise interventions on skeletal muscle and whole-body health outcomes, which may include invasive (e.g., blood and/or muscle biopsy samples) and non-invasive procedures (e.g., exercise tests or ultrasound scans) and may be acute (one or two study visits) or chronic (multiple study visits typically over ≥ 4-week period) in nature.

Materials and Methods

Ethics

Favourable opinion on this activity was provided by the University of Nottingham Faculty of Medicine and Health Sciences Research Ethics Committee (FMHS 82-0802) and volunteers were informed that participation in these activities constituted consent.

Activity design and volunteers

This activity consisted of two parts: i) an online questionnaire to obtain views from older adults (≥65 years) on participating in physiology research during the COVID-19 pandemic, and ii) online focus groups to explore these views further.

A total of 150 volunteers who had previously taken part in physiology research and had consented to their contact details being used for the purpose of being invited to future research were contacted via e-mail or post (past volunteers). A total of 400 volunteers who had not previously taken part in physiology research were contacted via post using demographically (age) targeted postal invites (potential volunteers). All volunteers were ≥65 years and lived

within the Derby/Nottingham (UK) area, as these postcodes were considered to be within a reasonable distance to the hospital research site (located in Derby).

The questionnaires (completed securely via Google Forms (Google Inc, California, USA)) consisted of Likert scale, multiple choice and free-text questions (past volunteer questionnaire: Figure S2; potential volunteer questionnaire: Figure S3). Questionnaires were distributed in September 2020 and all responses were received before the end of October 2020.

Subsequent to questionnaire completion, online focus groups (via Microsoft Teams (Microsoft Corporation, Washington, USA)) with semi-structured question guides were conducted, with discussions machine transcribed (Panopto Inc, Washington, USA), manually checked for accuracy and then thematically analysed following the established Braun & Clarke stages of thematic analysis (Braun and Clarke 2006). Focus groups were conducted in November 2020.

Statistical analysis

Percentages were reported for descriptive data sets. Likert data was analysed using unpaired t-tests with significance accepted as p<0.05. Data analysis was conducted using GraphPad Prism version 8 (GraphPad Software, San Diego, CA). Data are presented as mean \pm SEM.

Results

Online questionnaire

In total, 55 past (36 M, 19 F) and 57 (32 M, 25 F) potential volunteers completed the online questionnaire. Both cohorts were predominantly white (≥95%) and living within DE or NG (UK) postal codes. The majority of volunteers reported not having previously tested positive (past: 100%; potential: 93%) or having a suspected case of COVID-19 (past: 91%; potential:

84%). In the event of confirmed/suspected COVID-19 case, the majority of volunteers reported having returned to normal pre-COVID-19 activities (past: 91%; potential: 84%).

Both groups expressed a similar level of worry about contracting COVID-19 (p=0.27, Figure 1A) and each indicated that the research department being on a hospital site would have no impact on their decision to participate (p=0.50, Figure 1B). Related free text comments for this question are provided in Table S1. Compared to potential volunteers, past volunteers were more likely to consider taking part in both acute (p=0.04) and chronic (p=0.01) studies (Figure 1C and D). Those who said they felt unsure about taking part in physiology research were invited to provide a free text explanation for this uncertainty (Table S1). Interestingly, the majority of individuals in both groups reported that their feelings about taking part in both acute (past: 38%; potential: 40%) and chronic (past: 53%; potential: 49%) studies were not related to the pandemic, instead citing (e.g.,) time commitment as a reason related to participation hesitation (free text explanations are provided in Table S1). Our past volunteers had participated in acute (29%), chronic (15%) or both (56%) types of research studies, however the majority of these volunteers said they felt "no different" about taking part in a research study where they knew the researchers compared to where they did not (59%).

Although the majority of past (82%) and potential (88%) volunteers felt that the current COVID-19 safety measures already in place at research sites were adequate (listed as: i) enhanced cleaning, ii) mandatory face masks for researchers and volunteers, iii) one-way building movement, iv) minimal researcher numbers per volunteer and v) regular hand washing), further possible safety measures that would make volunteers more likely to participate were suggested in free text comments (Table S1). For example, one suggestion made by volunteers from both cohorts, was temperature checks on arrival at the research site.

The implementation of this suggestion is seemingly possible, as 100% of past and 93% of potential volunteers wouldn't object to having their body temperature recorded upon arrival to a research site (Figure S1A). The majority of both past (69%) and potential volunteers (68%) did not feel that face masks being worn by both researchers and volunteers would make communication difficult (Figure S1B), supporting the provision of, and obligation to, wear face masks during research study visits to minimise COVID-19 transmission.

Interestingly, both cohorts would be more inclined to participate in physiology research if both researchers (past: 71%; potential: 60%) and volunteers (past: 60%; potential: 51%) were regularly tested for COVID-19, including if this was done using 'in-house' diagnostic tests (e.g., PCR analysis of viral analytes from saliva), and so conducting these tests should be considered if possible (Figure S1C and D). Testing volunteers for COVID-19 antibodies (to see if they *previously* had COVID-19) would also make the majority of both past (62%) and potential (53%) volunteers more inclined to participate (Figure S1E). Interestingly, the majority of past and potential volunteers were neither more or less inclined to volunteer in research if it was COVID-19 related (Figure S1F), and the provision of an inconvenience allowance would not affect their decision to participate (past: 73%; potential: 72%). While most volunteers would travel to a research visit in a private car (past: 71%; potential: 74%) (Figure 2G), some would use public transport and indicated that they would feel safe to do so (past: 62%; potential: 78%) (Figure S1F).

Focus groups

Eight individuals participated in the volunteer focus groups, 5 (60% male) attended the past volunteer focus group and 3 (100% male) attended the potential volunteer focus group. Six higher order themes emerged from both volunteer focus groups, namely: i) positive attitude

towards volunteering during COVID-19, ii) concerns about volunteering during COVID-19, iii) research topic, iv) study design, v) trust and vi) agreement between volunteers (a summary of each theme is provided in Table S2). Each of these themes had *common* (i.e., shared between past and potential volunteer cohort) and/or *unique* (i.e., occurred in past *or* potential volunteer cohort) sub-themes (Figure 2A-F). An additional theme, familiarity, was identified in the past volunteers only, which specifically referred to volunteers having positive views towards revolunteering due to familiarity of the researchers and research facility (Table S2, Figure 2G)

Discussion

Clinical trials recruiting older adults are limited by the willingness of that population to volunteer in research, particularly during unprecedented times. To try and identify recruitment motivations/hesitations, we explored (using questionnaires) and probed further (via focus groups) the views of past and potential volunteers about participating in age-related physiology research during the COVID-19 pandemic. Our data shows that despite a level of concern, both volunteer cohorts demonstrated a positive attitude towards volunteering for physiology research during the current pandemic.

We found traditional motivations underlying willingness to participate, such as altruism (Manton et al. 2019), were evident across both cohorts, demonstrating that the provision of an inconvenience allowance was seemingly not a deciding factor in participation. Motivations related to COVID-19 were also expressed. For example, past volunteers viewed participating as less risky (in terms of contracting COVID-19) than going to the supermarket, and potential volunteers expressed that participating was an excuse to "get out and do something", most likely related to having been compliant with lengthy national lockdown periods that were in place for a large part of 2020 and have continued into 2021. In addition to these motivations,

we identified "trust" as a key theme emerging from our thematic analysis (i.e., the trust that volunteers have in research teams and in their ability to mitigate COVID-19 risk at a research site), which is likely linked to an increased willingness to participate. This finding supports previous work in the context of the influenza pandemic, in which Gobat et al. concluded that trust in health professionals increased willingness to participate (Gobat et al. 2019). Of course, it is possible that these largely positive views towards volunteering in research may change in line with fluctuations in the number of COVID-19 cases (Padala et al. 2020b), changing government guidelines and the recently launched national COVID-19 vaccination programmes (GOV UK 2020). Indeed, during the timeframe in which questionnaire's and focus groups were conducted (Sept-Nov 2020), COVID-19 cases were rising in both Derby and Nottingham, with the first week of November showing a particularly high number of cases (GOV UK 2021a). Thus, whilst only speculative, we propose that the views of older adults within our manuscript likely represent more conservative/cautious views in regard to volunteering during a pandemic. Furthermore, country-specific approaches to the COVID-19 pandemic have resulted in varied infection and death rates globally, and so the results herein may need to be treated with caution when extrapolating to other countries besides England.

Perhaps unsurprisingly based on the emergence of "trust" as a key theme, we found that past volunteers were more likely to consider taking part in both types (acute or chronic) of physiology research, compared to potential volunteers. Exploration of this question during focus groups revealed "familiarity" to be a key theme in this cohort. In particular, familiarity of the researchers and the research facility seemed to underpin positive views towards revolunteering.

Despite an overall positive attitude towards volunteering in physiology research, both volunteer cohorts expressed that their age was a concern, which is unsurprising since chronological ageing increases the risk of serious illness or death from COVID-19 (The Physiological Society 2020). Unique concerns were also expressed by each cohort, with asymptomatic viral carriage and building occupancy levels raised by past volunteers, and vulnerable family members and the precautionary actions of others (i.e., to prevent the spread of COVID-19) raised by potential volunteers. Reassuringly, many of these concerns appear to be able to be mitigated via the implementation of sufficient countermeasures, which may enhance the willingness of older individuals to participate in physiology research.

Considering more lethal strains of COVID-19 are continuing to emerge (e.g., B.1.1.7 (GOV UK 2021b)) and that similar challenges may arise in the future (e.g., severe influenza), understanding volunteer views in regard to their willingness to participate in physiology research during such circumstances looks likely to be relevant for some time to come. Herein, we found that although both past and potential volunteers had a generally positive attitude towards participating in physiology research during the COVID-19 pandemic, concern was still evident. These findings led us to provide the following practical recommendations to facilitate the successful recruitment of older adults during the current COVID-19 pandemic (and similar scenarios) during periods where national restrictions allow:

- Rigorously enforce relevant and current government COVID-19 guidelines (e.g., wearing face masks) and provide reassurance to volunteers that these guidelines are being implemented (e.g., via written and/or oral communications).
- Record body temperature measurements of researchers and volunteers when they arrive
 to the research site, only allowing study visits to go ahead if body temperature is within
 the normal range.

- If possible, conduct (in-house) COVID-19 testing of volunteers prior to each study visit, and regularly COVID-19 test researchers.
- If possible, conduct (in-house) COVID-19 antibody testing of volunteers prior to research participation.
- To promote familiarity among potential volunteers, provide an introductory video to familiarise volunteers with the research team and site, prior to their initial study visit.

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Competing interests

The authors declare there are no competing interests.

Author contributions

CSD, AG, GT-T, PJA and BEP conceived and/or designed the work; All authors contributed to the acquisition, analysis and/or interpretation of the data. CSD and BEP drafted the manuscript. All authors approved the final version of the manuscript and agree to be 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. All persons delegated as authors qualify for authorship, and all those that qualify are listed.

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Data availability statement

The data that support the findings of this study are available on request from the corresponding author upon reasonable request.

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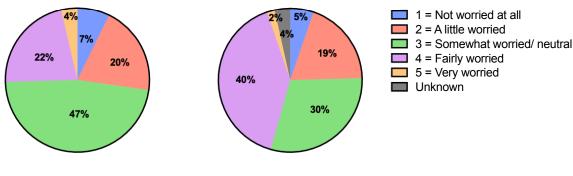
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Figure 1. Past and potential volunteer Likert scale answers to the online questionnaire. * indicates significant difference from past volunteers (p<0.05, unpaired t-tests).

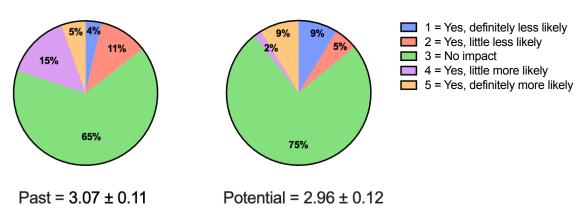
Figure 2. Themes and sub-themes derived from past and potential volunteer focus groups. Themes are indicated by bold underlined text, sub-themes unique to past or potential volunteers are indicated by a single blue or peach line, respectively. Common sub-themes are indicated by both a blue and peach line.



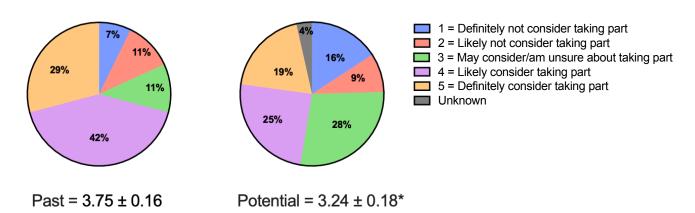
Past = 2.95 ± 0.13

Potential = 3.15 ± 0.15

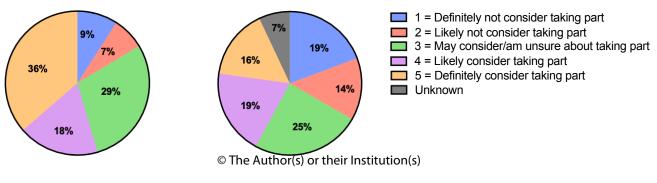
B Would the location of the research department being on a hospital site impact your decision to participate in physiology research?



C How would you feel about taking part in an 'acute' study?



D How would you feel about taking part in an 'chronic' study?



 $Past = 3.65 \pm 0.17$

Potential = $2.98 \pm 0.19^*$

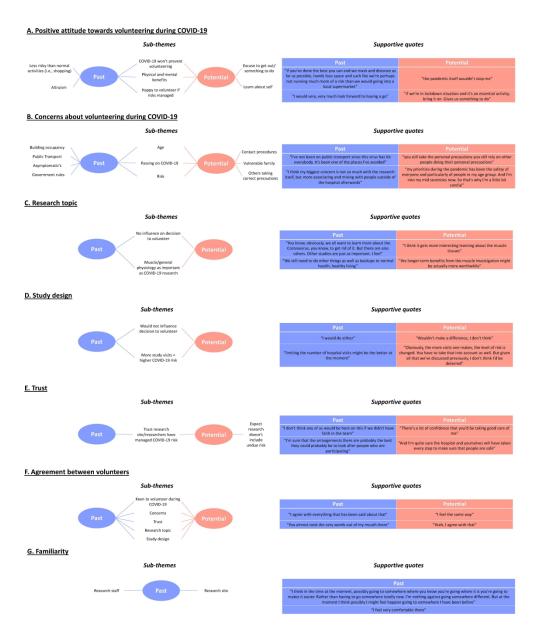


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199x237mm (600 x 600 DPI)