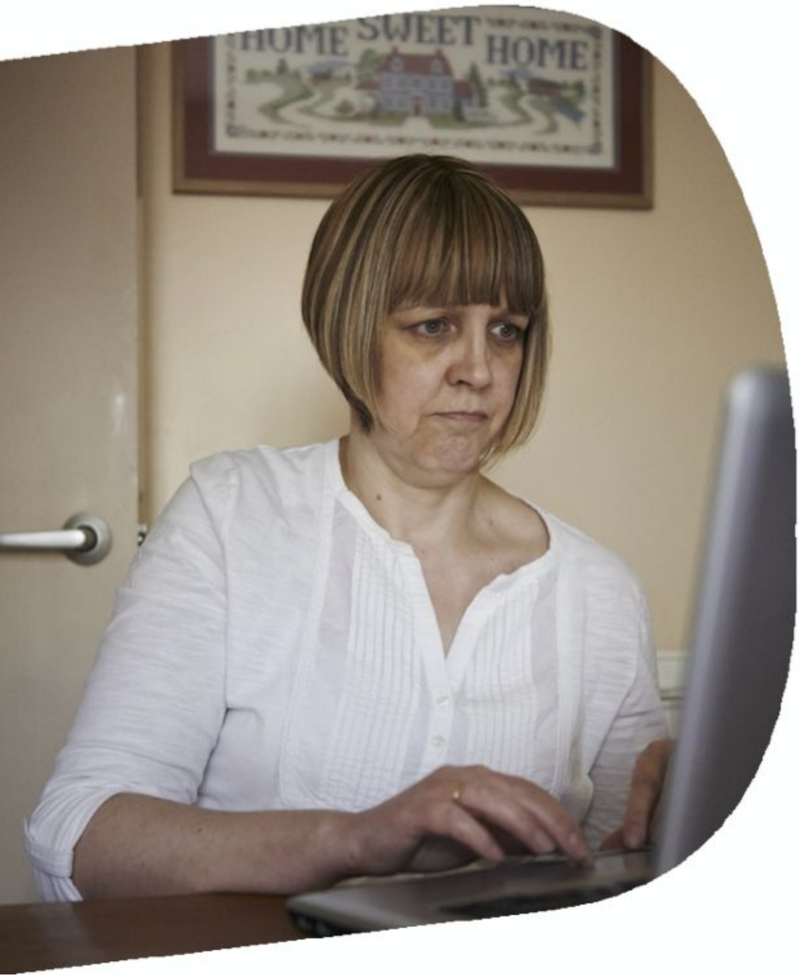
“We have to keep going.”

Driving research forward during Covid-19

Recommendations from people affected by Parkinson’s on adapting clinical research

October 2020



PARKINSON'S UK
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Acknowledgements

The Research Involvement team would like to thank the Involvement Steering Group for their valuable insights, and input on developing the survey and writing this report. We are grateful to everyone who completed the survey, and staff and supporters who shared the survey with their networks. Thanks also to the researchers, clinicians and research delivery staff who provided feedback on the survey questions

Executive summary

Clinical research studies are beginning to restart after many were paused or delayed because of the Covid-19 pandemic.

Parkinson’s UK conducted a survey to gather views from people affected by Parkinson’s about how research participation can be made safe and comfortable now and in the near future. The survey, which was co-created with researchers and people affected by Parkinson’s, was completed by 492 people with Parkinson’s and 56 carers/family members.

It is encouraging to see that respondents were generally positive about taking part in research and open to carrying out study assessments and other tasks in new ways— though it is crucial that participants receive appropriate guidance and support.

We hope the results and recommendations from the survey allow those involved in the design and delivery of research to adapt current studies and plan future projects. However, they are not a replacement for working with people affected by Parkinson’s to plan individual studies through patient and public involvement activities.

Researchers wanted to know...

Are people **happy to take part** in research at the moment?

91% of people said they are
Only 1% said they would not be

Where do people feel comfortable taking part?

Home visits from a researcher were the preferred option

Are people willing to collect **biological samples** at home?

- Blood - 93% yes
- Urine - 96% yes

What **measures** will help people **feel safe**?

- Social distancing
- Masks/visors
- Handwashing
- Avoiding public transport
- Researchers having regular Covid tests
- Clear researcher ID for home visits

Are people happy to carry out **study assessments** at home?

94% Yes

Online survey was the most popular method for questionnaires and other tasks

In partnership with people affected by Parkinson's and researchers, we have used the survey data to develop the following key recommendations for all those involved in the design and delivery of clinical research. There are also more detailed/specific recommendations throughout the report.

1 Provide participants with **clear information about Covid safety measures** that are in place
— this will provide reassurance, reduce anxiety, and enable informed decisions about research participation *[see 2.2]*

2 Adapt studies to **enable more data collection to be done from participants' homes**, where possible
— though options for participants should be flexible in order to ensure research is inclusive *[see 2.2, 2.4]*

3 Provide **additional information and up-to-date guidance** on what to expect from study participation
— people want to be prepared and know what to expect from research participation in the current climate *[see 2.3, 2.4, 2.5]*

4 Provide **extra support to help people with remote consultations** and at-home assessments
— people are keen to do research from home but remote consultations are new to many people *[see 2.4, 2.5]*

5 **Work directly with people affected by Parkinson's** to design and adapt studies
— each study will need specific considerations to ensure inclusivity and accessibility for those taking part *[see 3]*

1. Introduction

1.1. Background

When the Covid-19 pandemic began in the UK in March 2020, many Parkinson's clinical studies had to be put on hold. As strict restrictions now ease, steps are being taken to restart clinical research across the UK. It is vital that research resumes in a way that is safe for all involved, and comfortable and convenient for those who are taking part.

Clinical research will look different to before the pandemic, and as researchers look to make adaptations to existing studies and plan for new ones, it is important that they take into account the views of people affected by Parkinson's.

The aim of this work was to seek the views of people affected by Parkinson's on adapting research in order to inform researchers, clinicians and pharmaceutical companies who are redesigning existing clinical studies and/or designing new studies.

1.2. Method

Parkinson's UK conducted a UK-wide survey to seek the views of people affected by Parkinson's on adapting research studies in light of Covid-19.

The objectives of the survey were:

- to understand how people affected by Parkinson's feel about taking part in research in light of Covid-19
- to understand what adaptations may need to be made to the way studies are carried out to help people feel safe taking part in research
- to understand what support people affected by Parkinson's may need to be able to take part in research studies, in light of adaptations

1.3. Survey dissemination

The survey was shared directly with the Research Support Network via email and distributed to the local groups network via Parkinson's UK staff. It was also publicised on social media (Twitter and Facebook).

The survey was open to people with Parkinson's and carers, partners and family members of people with the condition. Carers, partners and family members were given the option to complete the survey either on behalf of the person affected by Parkinson's, or to share their own views — the latter option was included following feedback from a carer, highlighting that they may also be participants in research studies themselves. The survey was open from 28 July to 31 August 2020.

1.4. Stakeholder involvement

In developing the survey, it was vital to involve a range of different stakeholders in research to ensure that the questions asked were clear, relevant and useful.

The initial draft of the survey was developed in partnership with a small group of people affected by Parkinson’s, who provided input on questions, response options and the format of the survey. Feedback on the draft was sought from a wider group of people affected by Parkinson’s, researchers from academia and industry, clinicians and staff involved in research delivery.

1.5. Survey respondents

A total of 548 people were included in the analysis - 492 people with Parkinson’s, and 56 carers, partners and family members who completed the survey to share their own views.

Demographics snapshot

474 people provided demographic information.

- 75% of people were aged between 55-74 years old.
    - 9% were younger than 55
    - 16% were 75 or older
- More than half of the people with Parkinson’s were diagnosed between 1-5 years previously.
- 95% of people were from a White ethnic background.
    - Six people identified as Asian.
    - Twelve people selected ‘other ethnic minority’.
- 64% of people with Parkinson’s and 50% of carers, partners and family members had experience of taking part in research.

2. Findings and recommendations

2.1. Feelings about taking part in research

People were asked to what extent they agreed with the following statement:

> Generally speaking, I would feel comfortable taking part in a research study at present, or in the near future.

91% of people either strongly agreed (50%) or agreed (41%) with the statement, indicating overall a very positive perspective on taking part in research in the current environment.

This was supported by comments throughout the survey about the importance of research:

> *“I think it is important that research gets up and running again as soon as possible.”*
>
> *“I would like to do all I can to help research.”*
>
> *“Happy to take part.”*

For people with Parkinson’s, there was a higher percentage of “strongly agree” responses in the group who had participated in research before compared to those who hadn’t (55% vs. 39%).

Recommendations:

- Every effort should be made to resume Parkinson’s clinical studies that have been paused or delayed due to Covid-19.
- Researchers should provide additional information, support and reassurance to participants, particularly those new to taking part in research, and ensure this remains up to date.

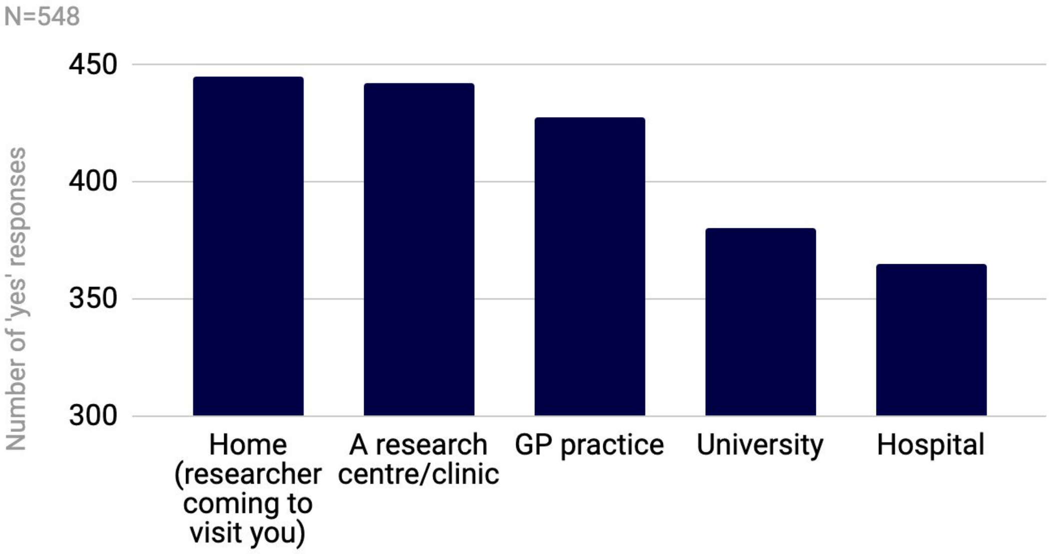
2.2. Taking part in face-to-face research

Most people indicated that they would feel comfortable taking part in research that involved face-to-face visits—providing that appropriate Covid safety measures were in place and adhered to.

A list of safety measures already in place/being considered by researchers was presented, such as maintaining social distancing as much as possible and wearing personal protective equipment. Participants were asked to state if there was anything else they thought would help to make visits feel safer.

The majority of people felt the measures were sufficient, and so did not add anything additional. Regular handwashing, temperature checks, and thorough cleaning protocols were noted in open text comments as important for face-to-face visits across all settings. A number of people also suggested that Covid testing for researchers and participants could help reassure people that taking part in research was safe.

The preferred setting for face-to-face visits was either the participant's own home or a research centre or clinic (separate from a hospital). Carers, partners and family members expressed more uncertainty about home visits compared to people with Parkinson's.



Hospitals were the least favoured venue, though the majority of people (67%) still said they'd feel comfortable taking part in research in hospitals. This was backed up by open text comments throughout the survey:

> *"Study centre or university would be ok. But I'd be very cautious about visiting a hospital at the moment."*
>
> *"I'd prefer not to be in a hospital setting but if absolutely necessary then the time needed for the appointment should all be in one room."*
>
> *"Worry about visiting hospitals due to possible high incidence of Covid-19 sufferers/carriers present."*

The majority of people thought that face-to-face visits should not last more than one (33%) or two (48%) hours.

Recommendations

- Researchers should inform study participants of the Covid safety measures that are in place, as this will provide reassurance and potentially reduce anxiety. Information should be written in plain language, and ideally in a range of accessible formats (e.g, written and verbal).
- Researchers should consider how hospital visits can be kept to a minimum - home visits should be offered where possible, or other settings should be considered. It is also important to give participants flexibility since individual circumstances differ.
- Face to face visits should be kept to a maximum of 2 hours where possible.

2.3. Additional considerations for research centre visits

Travel

Many people said that public transport should be avoided. Good parking facilities were repeatedly mentioned as necessary, and several people mentioned previous experience of difficulties parking at hospitals. It was recognised that driving would not be an option for some participants, so researchers should also offer to arrange transport for participants.

Appointment rooms

A number of people highlighted easy access to appointment rooms as important. People were keen to avoid busy areas and did not want to have to walk round buildings searching for rooms for longer than necessary.

Several people noted that research testing rooms can often be small and hidden away, particularly in hospitals. Good ventilation and space in testing rooms was considered important for being able to adhere to Covid safety measures.

Waiting times

People felt it was important to minimise waiting times indoors, and many people said they would not feel comfortable waiting in busy waiting areas, particularly inside hospitals. 80% of people said they’d be happy to wait outside, or in the car for those driving, until being called in to their appointment.

Attending appointments alone

Around a third of people indicated that they would not feel comfortable attending an appointment at a study centre/university/hospital without a carer, partner or family member. Several people noted that they would require assistance to travel, and others said that they’d prefer to have someone else present for support. However, people did recognise the importance of minimising the number of people present (including research staff). Ensuring flexibility on this aspect for those who need additional support is therefore important in order to avoid people being excluded from participating in research.

> *“I worry about hospitals, terrible places to get ill in, and researchers in [hospitals] I have found are not always treated with respect, being shunted from room to room...even managing the adaptations list above would be difficult.”*
>
> *“The parking and ease of travel would be top priority for me.”*
>
> *“I'd worry a little about reception areas. How busy would they be? Would there be some way of avoiding them? Perhaps being met outside and taken to the research centre/room via a different route?”*

Recommendations

- Resources should be in place to ensure that study participants are not required to travel to visits using public transport - such as convenient parking and the provision of private transport where required.
- Appointment rooms should be clearly signposted, easy to find and Covid safe.

2.4. Additional considerations for home research visits

Safeguarding

Many people highlighted the importance of researchers arriving at home visits with clear identification. Several people also said they would prefer to have a carer, partner or family member present with them during the visit.

Briefing about the visit

People felt it was important to be fully briefed ahead of the visit so they knew what to expect, and so they could prepare their homes (e.g. ensuring sufficient space, minimising interaction with other members of their household). Several people also said they would welcome instructions for cleaning their home after the visit.

Use of rooms/facilities

People noted that the number of rooms used by the researcher(s) during a home visit should be kept to a minimum. Weather permitting, outdoor visits could be a good option for those who have a private garden. Short visits (1-2 hours) were considered ideal to reduce the need for use of the bathroom. Advice around offering refreshments was also welcomed — under normal circumstances people would usually offer these but noted that it may be safer for researchers to bring their own.

> *“...a separate room in the home where participants and researchers can conduct assessments, so as to limit contamination risk and spread to other family members.”*
>
> *“Online would be best, though if a home visit is needed then that's okay as long as the person tests negative, wears PPE and washes their hands before and after the visit.”*

Recommendations

- Researchers should inform participants of safeguarding measures in place for home visits.
- Researchers should ensure participants are fully briefed ahead of visits so they are prepared, both for the research activity and for any necessary steps to comply with Covid safety measures.

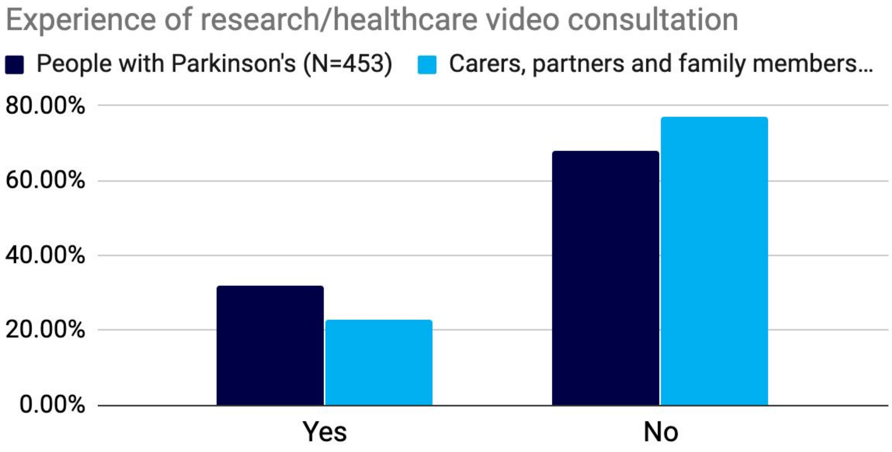
2.5. Completing study assessments at home

Over 90% of participants said they would be happy to carry out assessments at home. The preferred method for completing tasks such as providing general information, consent, medical history and answering questionnaires was via online survey. Half of participants said they would prefer to speak to someone over the phone or on a video call to report side effects.

The majority of people said they would be happy to do blood tests and urine samples at home, provided clear instructions were given. Carers, partners and family members expressed slightly more uncertainty about this compared to people with Parkinson’s.

Where participants would be required to perform physical activities for assessment (e.g., finger tapping or walking tasks), preference for how these should be done was mixed. 51% of people said they’d prefer to do these live over video, whereas 39% said they would rather these be done in person. Just 10% of people said they’d prefer to record themselves and send a video to the researcher.

The majority of people did not have experience of taking part in a video consultation as part of a research study or their healthcare.



People who had experience of taking part in research were more likely to have taken part in a video consultation compared to those that had not (23% vs. 8%).

Zoom was the preferred videoconferencing method.

There were a number of suggestions for making remote consultations and assessments easier:

Clear instructions

Many people said that having clear, detailed, easy to follow instructions on what was required for assessments was essential. Knowing what to expect in advance of the video consultation is important so that people can prepare. Video examples were suggested as useful.

Support with technology

A number of people expressed concerns at not being proficient with technology, and noted that the IT aspect could be a source of anxiety for some. Some also don’t have access to the right equipment so would need to be sent this.

Most people felt that technology challenges could be overcome with sufficient support and clear instructions, including the chance to speak with the researcher beforehand and do a ‘practice run’ to check the correct set up. Having a carer, partner or family member there for support would also be helpful. However it was noted that technology can be intermittent, and factors such as internet connection are difficult to remedy and can be a cause of frustration and anxiety.

Relationship building

People felt it was important for researchers to build up a rapport with participants in order to help them feel more at ease and supported. A number of people said they would appreciate the opportunity to have a phone call with the researcher prior to doing the remote assessments, in order to “get to know” the researcher and feel assured about the process.

> *“My husband would not be able to cope with the technology and would need a lot of help from me (the carer).”*
>
> *“I am not especially confident with computers so may need phone access at the same time to make sure it works okay.”*
>
> *“If I felt that everything would be conducted remotely and I did not have access to speak with someone regularly, I would probably hesitate to sign up.”*

Recommendations

- Researchers should offer flexibility for how study tasks and physical assessments can be done. Where things can be done remotely, this should be included as an option - though it’s important that participants are given choice in order to ensure research is inclusive.
- It is vital that researchers factor in additional time to support people with technology. Clear instructions are essential, and researchers need to be prepared to provide extra information and one-to-one support to ensure participants feel comfortable.

3. Further reflections

3.1. Survey sample

It’s important to consider the demographics of the survey sample and the potential biases that this could introduce to the insights captured. It is vital that those involved in the design and delivery of clinical research take demographic factors into account when considering study adaptations, and take appropriate steps to ensure that research is inclusive and accessible for everyone affected by Parkinson’s.

Engagement with research

The people who chose to take part in this survey were people who are typically already engaged in research - almost 50% of respondents were members of the Parkinson’s UK Research Support Network, and over 60% had previous experience of taking part in research. Given that people who hadn’t participated in research before reported being less comfortable with taking part in research at present or in the near future (see 2.1), it is reasonable to predict that the general enthusiasm for research seen amongst the respondents here would be somewhat reduced in a broader sample. As a result, the current findings may underestimate the level of information, support and guidance needed for people who are new to taking part in research.

Ethnicity

There is a distinct lack of ethinic diversity within the survey sample. 95% of respondents were from a White ethnic background. Six people (1.25%) identified as Asian, and 12 people (2.5%) of respondents selected “other ethnic background”. People from Black and Asian ethnic groups are disproportionately affected by Covid-19[1], and we also know that people from non-White backgrounds face additional barriers to research participation. The current findings neglect to take into account these differences.

3.2. Resource implications

There is recognition across the whole research community that many of the recommendations for adapting research will have resource implications, both in terms of direct financial costs and time. While all studies will have to meet Covid safety requirements, it may not be possible to implement all of the desirable measures which would make taking part in research more comfortable and convenient for participants. Each study will need to balance the costs, benefits and risks to the different options — and importantly, this should be done in partnership with people affected by Parkinson’s.

3.3. Potential for increasing research participation

Several people commented that home visits and remote consultations would likely be a lot easier and more convenient for many people, compared to the traditional approach of frequent face-to-face visits. Covid-19 has accelerated the adoption of remote consultations as a standard feature of clinical research design, and this has the potential to make research more accessible and increase engagement with research across the Parkinson’s community. It’s important to bear in mind that remote consultations can be a barrier to research participation for people who do not have access to technology, and so steps must be taken to prevent exclusion.

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[1] See The Lancet

4. Conclusions and next steps for research

The results of this survey can be used by all those involved in the design and delivery of clinical research to guide adaptations to existing studies and design new projects in light of Covid-19. In addition to making use of these broader insights and recommendations, we would expect individual research teams to be working directly with people affected by Parkinson's to discuss the design of the research. This can help ensure that any adaptations or new approaches are practical, convenient and agreeable for people affected by Parkinson's.

Parkinson's UK has a dedicated programme to support researchers across academia and industry to work with people affected by Parkinson's to shape research. For more information visit parkinsons.org.uk/ppiresearch or email us.

We hope that the recommendations will also be helpful and reassuring for people affected by Parkinson's who are considering and/or taking part in research.

> *"At the end of the day, there is a risk for people with parkinsons and a decision to be made about whether to do the research or not. That decision could be positively influenced if people felt more involved in the research via regular updates."*
>
> *"Speaking with people with Parkinson's individually as to how they would like to be involved and not using a one size fits all approach. "*

5. Further information

If you would like to see a more detailed analysis of the survey results, please email us at researchinvolvement@parkinsons.org.uk to request a full summary.

The following resources may be helpful—

For those involved in the design and delivery of research:

- A framework for restarting NIHR research activities which have been paused due to COVID-19
- HRA guidance - Making changes to a research study to manage the impact of COVID-19

For people affected by Parkinson's interested in or taking part in research:

- Parkinson's UK Take Part Hub - Find research for you
- NIHR guidance on keeping people safe during research appointments