

Optimising Treatment for High Blood Pressure in People at Risk of Adverse Events

Participant Information Leaflet

- We would like to invite you to take part in a research trial.
- Many people take medications to lower their blood pressure and reduce their risk of stroke and heart attacks.
- After many years, the benefits of taking these medications **may** become outweighed by the risk of falls and other side effects (otherwise known as 'adverse events').
- This trial is looking at the safety of reducing the number of medications prescribed to older people whose blood pressure is in the normal range.
- Before you decide if you would like to take part, we would like you to understand why the research is being done and what it would involve for you.

OPTIMISE2 Trial: Overview

1. Why have I been chosen? (See page 5)

Because you are aged 75 years or older and take two or more medicines that lower blood pressure. We would like to see if reducing the number of these medications can be done safely.

2. What will I have to do? (See pages 6-9)

If you agree to take part, you will be put into one of two equally sized groups. To try to make sure the groups are the same to start with, each person is put into a group by chance (randomly).

A:

A '**control**' group where nothing about your care will change

B:

An '**intervention**' group where you will have one or more blood pressure medication/s removed, decided by a doctor (or someone who routinely prescribes blood pressure medications)

There is a 1 in 2 chance you will be in the intervention group. During the trial, you will be asked to visit your GP surgery at least twice, for appointments with a doctor or the research team. It may be possible for the initial visit to be done remotely but any follow-up visits would need to be in person. During these visits you will be asked to answer some questions about yourself and complete some questionnaires. We will also measure your height, weight and blood pressure. If you are in the intervention group and your blood pressure is still in the normal range after stopping one medication, your doctor may decide it is appropriate to stop another one. This would involve another follow-up visit 4 weeks later. Your active involvement in the trial will last for 12 months. At the end of this period we will send you some questionnaires to complete.

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3. What is the intervention being tested?
(See page 10)

If you are allocated to the intervention group, you will stop taking one of the medications you take to lower your blood pressure. You may be asked to stop taking more than one but only one at a time.

4. Risks and benefits of participation
(See page 11)

If you are in the control group, you would continue to receive standard care. There are no additional risks or benefits to being in this group. If you are in the intervention group, your blood pressure could rise, leading to an increased risk of heart attack or stroke. However, your blood pressure will be monitored carefully so the likelihood of this happening is very low. Those in the intervention group may be less likely to suffer side effects from medication, such as falls.

5. Stopping participation in the trial
(See page 12)

You are free to leave the trial at any point and your decision to do so will not affect the treatment you receive from your GP. You may restart your blood pressure medication (if you are in the intervention group), withdraw from visits/questionnaires only, or leave the trial completely and request that we collect no more follow-up data (unless needed for safety reasons).

6. What to do if there are problems
(See page 15)

If you have any queries about this trial then please contact the trial management team on 0808 196 8649 or email optimise2-trial@phc.ox.ac.uk
If you wish to complain about any aspect of the way in which you have been treated during the trial, you should contact the Trial Manager, or the University of Oxford's Research Governance, Ethics & Assurance (RGEA) office on 01865 572224 or email RGEA.Sponsor@admin.ox.ac.uk.

7. Confidentiality
(See pages 13-15)

In this research study we will use information from your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data in case we need to check it or for future research. We will make sure no-one can work out who you are from the reports we write.

8. What will happen to the results of the trial?
(See page 16)

The results of this research trial will be published in a scientific medical journal and on the study website.
www.optimise2.org

9. Who funded and approved the trial?
(See page 16)

This trial is being funded by the National Institute for Health Research Health Technology Assessment. It has been reviewed and given favourable opinion by East Midlands - Leicester Central Research Ethics Committee.

Thank you for considering taking part in this trial.

OPTIMISE2 Trial: Full Details

What is the purpose of the trial?

The population of the UK is getting older and more people are living with multiple illnesses, taking lots of tablets to manage these illnesses. High blood pressure is one of the most common medical conditions in older people and many take two or more medications to treat it.

Recent scientific studies suggest that too many drug prescriptions together with lower blood pressure, may be associated with an increase in falls and death in older patients. Our previous trial showed that reducing the number of blood pressure lowering medications prescribed to older people is safe over a three-month period.

We want to know what the longer-term effects of stopping blood pressure lowering medications are and make sure our results are fair by including a lot more people. This trial aims to look at this in people aged 75 years or older, who are at a higher risk of drug-related side-effects, are taking two or more medications and have blood pressure in a normal range.

Why have I been invited to take part?

You have been invited to take part because you have, or have in the past, had high blood pressure and your doctor has given you medications to reduce it. Now that you are older, the benefits of reducing your blood pressure may be outweighed by the side effects of taking two or more medications (for example, an increased risk of falling over). We would like to recruit 3,014 people like this, to see if reducing the number of blood pressure lowering medications you take can be done safely, and possibly improve your quality of life.

A GP has reviewed our trial criteria and identified you as someone who might be eligible.

Do I have to take part?

No. The trial is voluntary. It is up to you to decide if you want to take part and if you do, you are free to change your mind at any time, without giving a reason. This would not affect the care you receive.

What will happen to me if I take part?

If you decide to take part you will be invited to a consultation with a GP or other clinician who routinely prescribes medications for blood pressure. If face-to-face visits are not possible, this may be done remotely by telephone or using the surgery's information governance (IG) approved video conference software. They will give you some more information, explain what you would have to do and answer any questions you have. *If you would like to participate you will be asked to sign a consent form.* If you feel unsure you can ask to have another consultation and longer to think before starting the trial. If this consent visit is done remotely you will be sent an email link to complete and sign the consent form using a finger or stylus on your device.

Once you have signed the consent form, a trained researcher will ask you some basic questions about yourself (e.g. ethnicity), so that we can make sure our trial is giving us information about everyone fairly, and about your medical history. They will also take some measurements of your height, weight and blood pressure. If this visit is remote then we may ask you to measure these yourself, or we will use the most recent record from your clinical notes. Finally, if you are suitable to take part, you will be asked to complete some simple questionnaires about your daily activities and general quality of life.

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**What will
happen to me
if I take part?
(Continued)**

Following this, you will be put into one of two equally sized groups. Nobody can choose which group you will be in. This is to make sure the study is fair and gives reliable results. We need to compare the different treatments. So, we put people into groups and give each group a different treatment. The results from the different groups are compared to see if one is better or if they are even. To try to make sure the groups are the same to start with, each patient is put into a group randomly.

If you are allocated to the 'control' group, you will continue to take your medications as normal, nothing will change.

If you are allocated to the 'intervention' group, you will be asked to stop taking one of your blood pressure medications immediately. The medication will have been decided by a doctor or prescriber based on the medicines you take and what they are for. If your blood pressure is still stable 4-weeks later you might be asked to stop another but only one change at a time. Each time you stop taking a medication you will be booked for another visit 4-weeks later to check your blood pressure and for any side effects. If you have any health concerns after having your medication stopped please contact your GP or local trial team before the 4-week safety visit. *There is a 1 in 2 chance you will be in the group taking fewer medications to lower blood pressure.*

Both groups will be invited back for the follow-up visit at 4 weeks and then asked to complete a questionnaire after 1 year. The questionnaire can be completed online by clicking a link in an email sent by us or it can be done on paper and we will give you a pre-paid envelope to send it back. If you have questions or would like help completing

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**What will
happen to me
if I take part?
(Continued)**

this questionnaire then a member of the trial team can help via phone.

For the 12 months you are taking part you will remain in the same group you are assigned to at the beginning. You will need to continue as advised by the trial team unless your GP gives other advice. You can continue any other medication you normally take.

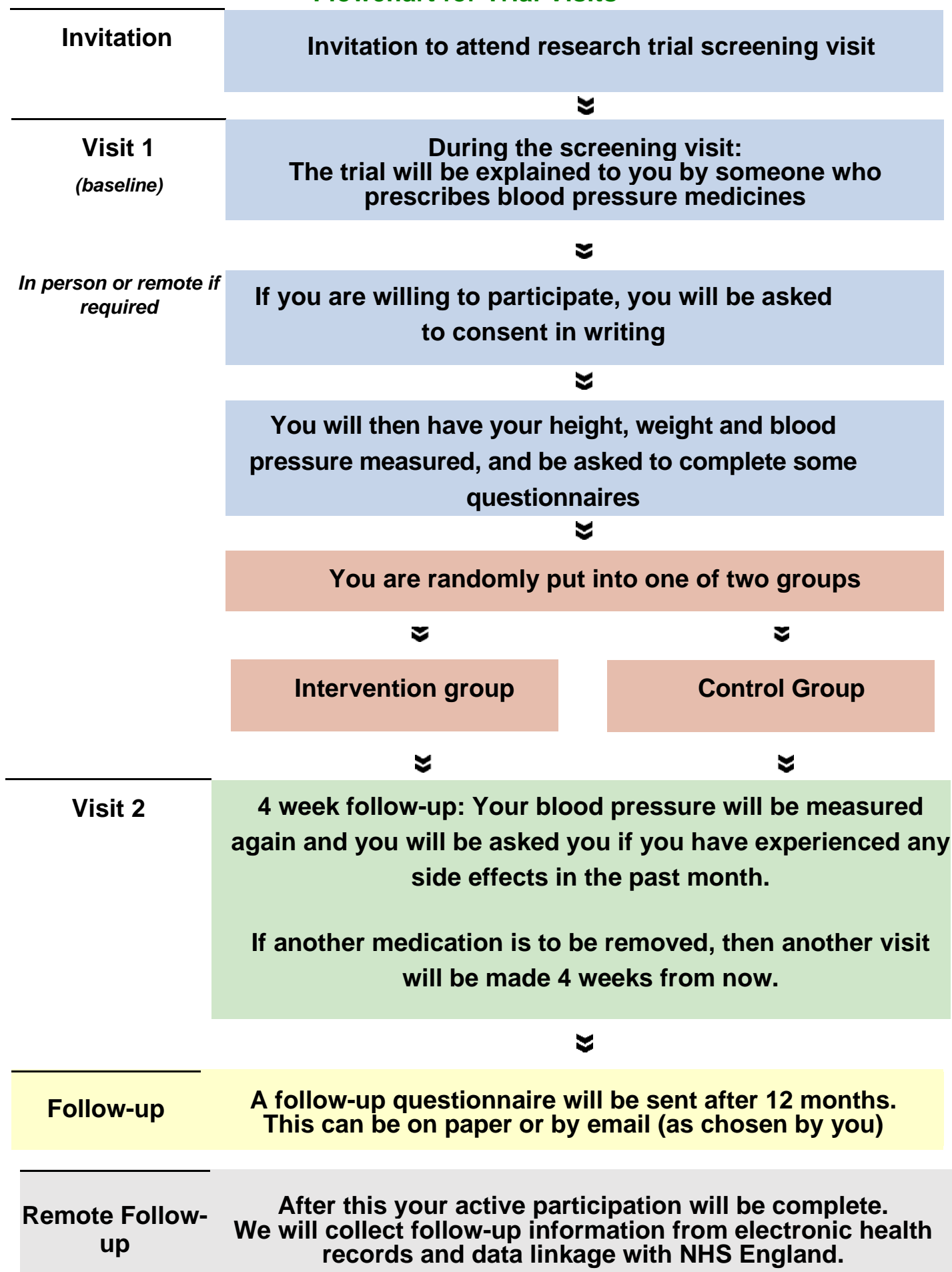
**What should I
consider?**

There are some reasons that you may not be able to take part in the trial, including:

- Heart failure diagnosis
- If you have suffered a heart attack or stroke within the past 6 months.
- If you are participating in any other trial of drug treatment or interventional medical devices in the past 4 weeks.

All criteria will be reviewed to ensure eligibility.

Flowchart for Trial Visits



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What is medication reduction?

Medication reduction is where you stop taking a medicine you have been prescribed on the advice of a medical professional. If you are allocated to the intervention group in the trial, you will stop taking one of the medications for lowering your blood pressure. This medicine will have been chosen by a GP or prescriber based on your medical history. They will look at whether you have ever experienced any side effects taking the medication, or if there is a chance that it might react negatively with some of the other medication you take. If neither is the case, they may choose to stop the medication you were most recently prescribed. They will discuss this medication reduction plan with you at your first visit before you are asked to agree (consent) to the trial but they will not tell you which medications they have chosen to stop. You will only be told this if you sign the consent form to agree to take part, and then are randomly selected for the intervention group. If your blood pressure is still in a normal range 4 weeks after the medication has been stopped, they may decide to stop another one. Every time they stop a medication, they will monitor your blood pressure carefully and invite you for a 4-week follow-up visit.

Expenses and Payment

You will not be paid for taking part in the trial. However, you will have made a valuable contribution towards research and helped to develop better ways of caring for people with high blood pressure as they get older.

What are the risks and benefits of taking part in this trial?

Risks of taking part

1. All participants in this trial will receive normal routine care from their GP. If you are in the control group, you will be at no further risk (compared to standard care) by taking part.

2. Medications which lower your blood pressure also lower your risk of having a heart attack or stroke. Thus, if you are in the intervention group and one is removed, your blood pressure may rise and, you could be at risk of suffering a heart attack or stroke (an adverse event) if this were left unchecked. With the withdrawal of certain medications there may be a risk of palpitations, peripheral oedema (excess fluid causing swelling), or prostatism (swelling of the prostate gland - only relevant for people with prostates).

3. In this trial, you will see/speak to the medical team at regular intervals. If your blood pressure does increase significantly, your medications will be reintroduced, *rendering the likelihood of you suffering an adverse event very low.*

Benefits of taking part

1. If you are in the control group, there will be no clear additional benefits for you taking part in the trial. However, you will have contributed to research which helps to develop better ways to care for people with high blood pressure as they get older.

2. If you are in the intervention group and have your medication removed, you may be less likely to fall over or suffer other side effects which affect your quality of life. We will not know if this is the case until after the trial is finished.

What if I become unwell during the trial?

If you become unwell, need to attend hospital for any reason or change your normal medication whilst you are in the trial you should inform your GP. We will need to record this in our trial documents so it would be helpful if you could also notify the trial team at your practice. If you are in the intervention group and become unwell as a result of having your medication reduced, you may be asked to start taking that medication again.

You can request to start taking your medication again at any time.

What happens to me after the research visits are finished?

Your active participation in the trial will continue for 12 months but you will only need to attend in-person visits for as long as there are any changes to your medication. After this you will be followed up by the research team for a period of up to 10 years after you join the trial. They will use your medical records and data held about you in central NHS registries and databases (including NHS England). This will be used to collect information on any hospital admission or other relevant health condition/s that you may have during the follow up period. Your blood pressure will continue to be managed by your GP, and this may include continuing/starting medication reduction where appropriate.

What if new relevant information becomes available during the trial?

Sometimes we get new information about the treatment or strategy being studied. If this happens, the team will tell you and discuss whether you should continue in the trial. If you decide not to, your care will continue as usual. If you decide to continue they may ask you to sign a new consent form outlining the discussion and that you are happy to continue.

What will happen if I want to stop taking part in the trial?

You are free to leave the trial at any point. Leaving the trial will not affect the treatment you receive from your GP. If you have any concerns once you have left the trial you can contact the research team for help and advice.

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How will we use information about you?

Data protection legislation requires that we, the University of Oxford (whose legal name is The Chancellor Masters and Scholars of the University of Oxford), state the legal basis for processing information about you. In the case of research, this is a 'task in the public interest'. The University of Oxford is the sponsor for this study and is responsible for looking after your information and using it properly.

We will need to use information from you and your medical records for this research project. We will share your information related to this research project with the following types of organisations: your GP practice, Research Delivery Networks.

This information will include your initials, NHS number, Date of Birth, name, and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure by:

- Making sure all data will be kept securely according to the UK General Data Protection Regulation (GDPR) and Data Protection Act 2018
- Securely storing all data on a password protected database. Only the research team will be able to access the information.

Your personal data will not be shared outside the UK.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our

How will we use information about you? Cont.

reports in a way that no-one can work out that you took part in the study.

We will keep your study data for the minimum period of time required by the University Policy on Management.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records and your GP. If you do not want this to happen, tell us and we will stop.

You can find out more about how we use your information by:

- asking one of the research team
- sending an email to optimise2-trial@phc.ox.ac.uk
- calling us on 0808 196 8649
- contacting the University's Data Protection Officer data.protection@admin.ox.ac.uk
- looking at the University's privacy notice available at: <https://compliance.admin.ox.ac.uk/research-data>

If you would like to find out more about the use of confidential data in research, the HRA has developed a general information leaflet which is available at: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/>

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. We will hold your personal information only for as long as needed to inform you of the results of the trial and then this will be deleted. We will keep your anonymised study data for a maximum of 10 years. The study data will then be securely archived.

What if there are any problems?

If you have any queries about this trial then please contact the Trial Manager (see contact details on page 16).

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this trial, you should contact the Trial Team (see page 16), or you may contact the University of Oxford Research Governance, Ethics & Assurance Team (RGEA) office on 01865 572224 or email: RGEA.Sponsor@admin.ox.ac.uk

The NHS Patient Advice and Liaison Service (PALS) is available at <http://www.pals.nhs.uk/> PALS is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment with which you are provided.

What will happen to the results of the research trial?

The results of this research trial will be published on the trial website (www.optimise2.org) and in a scientific journal, sometime after the trial has finished. Your individual results will not be identifiable nor would you be identified in any report or publication. Your GP will have access to your personal results, which will be stored in your medical notes, and will address any that are unusual.

Who is organising and funding the research?

This trial is being funded by the National Institute for Health Research (NIHR) Health Technology Assessment. The trial is being run by Primary Care Clinical Trials Unit, Nuffield Department of Primary Care Health Sciences, University of Oxford.

Who has reviewed the trial?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This trial has been reviewed and given favourable opinion by East Midlands - Leicester Central Research Ethics Committee. Members of the OPTIMISE2 Patient & Public Involvement Group have reviewed this leaflet and contributed feedback.

This trial has also received approval from the Medicines and Healthcare products Regulatory Agency (MHRA).

Further information and contact details

If you would like any further information about this trial you can call the research team on 0808 196 8649 or e-mail us at optimise2-trial@phc.ox.ac.uk

Our Contact Details

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