

**FULL/LONG TITLE OF THE STUDY**

Sedentary time in individuals with ischaemic heart disease and its association with cardiac function, structure and cardiovascular risk factors.

**SHORT STUDY TITLE / ACRONYM**

- Sedentary time cardiovascular risk factor associations in IHD

**PROTOCOL VERSION NUMBER AND DATE**

- V11.0/ 02Dec22

**RESEARCH REFERENCE NUMBERS**

<b>IRAS Number:</b>	312557
<b>SPONSORS Number:</b>	N/A
<b>FUNDERS Number:</b>	N/A

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**SIGNATURE PAGE**

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

**For and on behalf of the Study Sponsor:**

Signature:

.....

Date:

...../...../.....

Name (please print):

.....

Position:

.....

**Chief Investigator:**

Signature:

.....

Date:

...../...../.....

Name: (please print):

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**KEY STUDY CONTACTS**

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Committees	N/A
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**STUDY SUMMARY**

Study Title	Sedentary time in individuals with ischaemic heart disease and its association with cardiac function, structure and cardiovascular risk factors.
Internal ref. no. (or short title)	Sedentary time and cardiovascular risk factors in IHD
Study Design	Cross-sectional
Study Participants	Ischaemic heart disease patients
Planned Size of Sample (if applicable)	67
Follow up duration (if applicable)	7 days
Planned Study Period	7 days
Research Question/Aim(s)	What is the sedentary pattern of individuals with ischaemic heart disease and its association with cardiac function and cardiovascular risk factors?

**ROLE OF STUDY SPONSOR AND FUNDER**

The Sponsor of this study is the University of Bedfordshire. The sponsor is responsible for the overall conduct and management of the study

There is no external funder for this study.

**ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS**

**Cardiac Rehabilitation Team at Bedford Hospital**

Regular meetings will be held between the Bedford Hospital Cardiac Rehabilitation team and the study investigators to discuss how to conduct the study in terms of participant recruitment, data collection and dissemination.

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**PROTOCOL CONTRIBUTORS**

Abbie Bell

PhD Student

Institute for Sport and Physical Activity Research

Responsibilities: Study design, study conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

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Responsibilities: Overview of study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results

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Responsibilities: Overview of study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results

Dr Daniel Bailey

External Advisor

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Responsibilities: Overview of study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

**KEY WORDS:**

Ischaemic heart disease (IHD), Coronary artery bypass graft (CABG), Post- myocardial infarction (post-MI), Cardiac Rehabilitation (CR), sedentary behavior, cardiometabolic risk

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## STUDY PROTOCOL

### 1 BACKGROUND

Cardiovascular Disease (CVD) is the leading cause of mortality and morbidity globally (World Health Organization, 2019). In the UK alone, it was accountable for 124,641 deaths in 2017. Further to this, CVD contributes to a vast economic burden, costing the National Health Service (NHS) £19 billion annually. This is mainly due to a significant number of hospital readmissions following a first cardiac event (198,000 per annum) (British Heart Foundation, 2018).

Cardiac Rehabilitation (CR) is a secondary preventative measure to further cardiac events. The British Association of Cardiovascular Prevention and Rehabilitation (BACPR) defines CR as 'the coordinated sum of activities required to influence favourably the underlying cause of cardiovascular disease, as well as to provide the best possible physical, mental and social conditions, so that the patients may, by their own efforts, preserve or resume optimal functioning in their community and through improved health behaviour, slow or reverse progression of disease'. It is suggested by the National Institute for Health and Care Excellence (NICE) that all patients should be offered a CR programme with an exercise component following an MI (BACPR., 2017). There is conflicting evidence regarding the benefits of exercise-based CR upon cardiovascular mortality and morbidity, hospital readmissions and all-cause mortality. Previously, CR has been shown to be beneficial in longer term health outcomes of cardiac patients. The 2016 Cochrane Review of Exercise based CR found that, when compared with a no exercise control group, exercise-based CR accounts for an estimated risk reduction of 26% and 18% for cardiovascular mortality and hospital admissions respectively, but no reduction in total mortality or further cardiovascular events (Anderson et al., 2016). Despite BACPR recommending reducing sedentary behaviour following a cardiac event, there is scarce evidence regarding the association of sedentary behaviour with cardiovascular risk or cardiac related outcomes in this population group (Freene et al., 2022).

Sedentary behaviour is defined as a waking energy expenditure of  $\leq 1.5$  METs (metabolic task equivalent) while in a seated, reclined or lying posture (Tremblay et al., 2017).. Due to technological advancements and changes in social norms and workplace behaviours, many population groups engage in high amounts of sedentary behaviour. For instance, in 1377 older men in the UK, self-reported data showed an average of 317 minutes per day of TV viewing, reading, commuting and car use {Jefferis, 2016 #265546}. Further to this, accelerometer derived findings within this study reported an average of 619 minutes per day of sedentary time in older men (Parsons et al., 2016). An international study of 49,493 participants from 20 countries across the world reported a median of 300 minutes per day of sitting (Bauman et al., 2011). However, studies using self-report methods are limited as individuals typically underestimate their sitting time. This may underestimate the true magnitude of association

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between sitting time and cardiovascular risk markers. A comparison study of a self-reported questionnaire (international physical activity questionnaire (IPAQ)) and an activPAL accelerometer upon sitting time confirms this, where the IPAQ was found to underestimate sitting time by 3.4 hours per day (Chastin et al., 2014). Hence, estimating sitting using device-based methods is important in contributing to knowledge regarding associations with health outcomes (Celis-Morales et al., 2012).

Sedentary behaviour is associated with cardiovascular risk markers in the general population. Within the US National Health and Nutrition Examination Survey (NHANES) survey, a detrimental linear association was found between total time spent sedentary and waist circumference, high density lipoprotein cholesterol (HDL-C), triglycerides, insulin, insulin sensitivity and  $\beta$  cell function (Healy et al., 2011). In addition, independent of total sitting time, a higher number of breaks in sitting per day was significantly beneficially associated with waist circumference, C-reactive protein and fasting plasma glucose (Healy et al., 2011). Therefore, both reducing total sedentary time and frequently breaking up prolonged periods of sedentary time are associated with improved cardiometabolic risk in the general population (Healy, et al., 2011). Further to this, a meta-analysis which reviewed the association between sedentary behaviour and blood pressure (BP) had somewhat varied findings (Lee & Wong, 2015). Of the 31 articles included, 18 articles found no association between sedentary behaviour and either systolic blood pressure (SBP) or diastolic blood pressure (DBP). Typically, those that did not find a significant association between SB and BP had a smaller sample size, and SB was objectively measured. Despite this, the subsequent meta-analysis (n=28) showed a significant association between SB and BP, of which every additional hour of SB per day was associated with an increase in 0.06 mmHg for SBP and 0.20 mmHg for DBP with an odds ratio of 1.02 (95% CI 1.00-1.03, p=0.02) for high blood pressure (both SBP and DBP). All studies adjusted for confounding variables, including age and sex, but some studies adjusted for more confounders than others (Lee & Wong, 2015). It is important to note that null findings were more prominent in studies that adjusted for moderate to vigorous physical activity, a historically known influence upon BP (Pescatello et al., 2004). However, these studies have typically been conducted in the general population, healthy individuals, or those who are overweight/ obese. There are currently limited studies that investigate the associations of sitting with cardiovascular risk factors in a population who have ischaemic heart disease. Furthermore, there appear to be no studies that have investigated the association of sitting time with cardiac function in this group, which is important to inform the potential importance of targeting reductions in sedentary behaviour as part of cardiac rehabilitation. Therefore, the aim of this study is to determine the prevalence of device measured sitting and the association of sitting with cardiovascular risk factors and cardiac function in individuals who have ischaemic heart disease.

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#### **4 RESEARCH QUESTION/AIM(S)**

- 1) How much time do individuals with ischaemic heart disease spend sitting per day?
- 2) What is the association of daily sitting with cardiac function, structure and cardiovascular risk factors in ischaemic heart disease?

##### **4.1 Objectives**

- 1) To identify daily sitting time in individuals with ischaemic heart disease in the first year of their cardiac recovery.
- 2) To establish objective associations of sitting time with cardiac function, structure and cardiovascular risk factors, including anxiety and depression.

#### **5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS**

##### Study protocol

An observational, cross-sectional study design will be used. Participants can have preliminary measures taken either during a visit to the Sport and Exercise Sciences Laboratories at the University of Bedfordshire or in their own home, depending on the participant's preference. This consists of anthropometric measures (height, weight and waist circumference). Participants will then rest for 5 minutes to achieve a steady state before baseline blood pressure is taken. Baseline cardiac function measures will be measured using an echocardiogram scan, as well as an electrocardiogram (ECG) to ensure there are no electrical contraindications to the heart (including new ST depression / elevation or any arrhythmias) which would make the participant unsuitable to complete the study. Mood and wellbeing measures will then be assessed using questionnaires.

Following this, participants will be asked to complete 7 full days of normal daily activity, whilst wearing an activPAL monitor on their thigh to record sitting, standing and stepping. The main data collection will take place at the participant's home, workplace or leisure setting (i.e. under free-living conditions), with social distancing in place if required at the time of data collection. Instructions will be given to help ensure that the 7-day monitoring period reflects their usual habits. The monitoring period will also be carefully decided, to ensure it does not conflict with any events that are out of the usual for the participant, such as holidays or work-based events, which would alter their usual sedentary patterns.

##### Data collection

##### *Demographic data*

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Patient demographic data will include age, gender, diagnosis and intervention. This is routinely collected within Cardiac Rehabilitation as part of their usual standard of care.

### *Height and weight*

Equipment to measure height, weight and waist circumference will include a stadiometer (Leicester Height Scale, Marsden HM-250P, Leicester, UK) to measure height in cm, a measurement tape for waist circumference and digital weighing scales (Tanita, BWB0800, Allied Weighing, UK) to measure weight in kg.

### *Blood pressure and heart rate*

Blood pressure and heart rate will be measured in an upright, seated position using an automated device (Omron M5-1 automated oscillatory device, Omron Matsusaka Co. Ltd., Matsusaka, Japan). The left arm will be used to measure blood pressure unless there is preference for the right arm due to any potential previous medical conditions. Two measures will be taken, with 5 minutes apart.

### *Cardiac function*

In a laboratory or in the participants home, the participant will be asked to undress from the waist up and lay on the medical couch in the left lateral decubitus position. Here, a scanning gel will be applied to the echocardiogram probe. This forms part of the echocardiogram system (Esoate, MyLab Omega, Italy). Parasternal and apical views will be acquired (Armstrong and Ryan., 2012). Once these images are collected and stored, the gel will be removed from the probe and chest. All images will be stored anonymously, where participants will be given a participant ID number. All image analysis will be completed using Echopac software (GE Healthcare, Version 113, GE healthcare, Chicago, Illinois, United States). Measures taken from the echocardiogram scan will be used to calculate left ventricular structure and function.

### *Anxiety and Depression*

The Hospital Anxiety and Depression Scale {Zigmond, 1983 #285206} will be used to assess feelings of anxiety or depression.

### *Measurement of sitting, standing and light physical activity*

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Following preliminary measures, sitting, standing and stepping will be monitored 24 h/day over seven full days using an activPAL activity monitor (PAL Technologies, Glasco, Scotland). This will measure changes in posture and level of activity by cadence. The activity monitor will be attached to the skin with a waterproof dressing on the anterior right thigh. The Processing PAL application will be used to process the data collected from the activPAL device. It uses a validated algorithm to isolate waking and sleeping time and to generate the outcome data. Participants will also be given a 7 day activity diary to record waking times, and other relevant activities to cross-validate the Processing PAL measured sleep and wake times.

### **Data analyses**

Statistical analyses will be conducted using SPSS Version 28 (IBM, Armonk, NY, USA). Descriptive statistics will be reported as mean and standard deviation (SD). Data will be checked for normality across each category using quantile-quantile plots. Total sitting time, breaks in sitting, standing and light, moderate and vigorous intensity physical activity, and total number of sit to stand transitions (frequency of breaks) data will be presented as mean and SD and also expressed as a percentage of daily waking time.

Correlation coefficients will be used to explore relationships of sedentary time variables with cardiac and cardiovascular risk factors. Multiple regression analysis will be used to model each aforementioned independent variable separately with cardiovascular risk factors (blood pressure, BMI, waist circumference, anxiety and depression) and measures of cardiac function and structure. It will also be used to explore associations between sedentary time with cardiovascular risk factors and cardiac function and structure, adjusting for potential confounding variables, including type of condition, time since diagnosis of cardiac condition, age, gender, ethnicity, and socioeconomic status, and whether any measures are confounding variables to the association between sedentary time with cardiovascular risk factors and cardiac function and structure.

## **7 SAMPLE AND RECRUITMENT**

### **7.1 Eligibility Criteria**

#### **7.1.1 Inclusion criteria**

- Patients diagnosed with *ischemic heart disease* within the past 12 months (within National Audit of Cardiac Rehabilitation (NACR) outcome data). This includes post myocardial infarction (ST wave elevated MI or Non-ST wave elevated MI), post coronary artery bypass graft, post percutaneous coronary intervention.

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- Males and females
- Aged 18 years or above.
- Any ethnicity.

### **7.1.2 Exclusion criteria**

- Under 18 years of age.
- Unable to provide valid informed consent (lack of mental capacity).
- Not had a cardiac event diagnosed within the past 12 months.
- Unstable coronary disease.
- Disease or conditions with a prognosis of less than 6 months to end of life (palliative care).

## **7.2 Sampling**

### **7.2.1 Size of sample**

An estimated sample size was calculated using G\* Power (version 3.1.9.4). Based on previous data (Carson et al., 2014), it was estimated that 67 participants would be needed to detect a medium correlation coefficient ( $r$ ) of 0.3 between sedentary time and cardiac outcomes with 80% power at an alpha level of 5%. If drop out occurs, participants will be replaced to ensure minimum recruitment is met. This decision will be pragmatic in accordance with study timeline.

### **7.2.2 Sampling technique**

Eligible patients will be approached during Phase 1 and 2 of Cardiac Rehabilitation or via advertisements (posters, social media posts, email). Convenience sampling will be used to ensure sufficient recruitment to the study.

## **7.3 Recruitment**

### **7.3.1 Sample identification**

Participants will be identified by a member of the University research team who will regularly attend CR initial assessment telephone clinics. This member is also employed at Bedford Hospital as a Cardiac Rehabilitation Exercise Specialist. They will have access to the clinic list and medical notes prior to the consultation, where they can be screened to check who may be eligible for the study. This is usual practice as part of the role of a Cardiac Rehabilitation Exercise Specialist. All members of the research team involved in recruitment will have an NIHR research passport and will have completed secondary

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GCP (Cardiac Rehabilitation Exercise Specialist). Eligible patients will be approached by the Cardiac Rehabilitation Exercise Specialist to ask if they would be interested in volunteering to take part in the study via telephone.

Participants will be approached after their initial CR appointment by a member of the research team to invite them to take part in the study via telephone. An introduction to the study will be given and the patient will be sent a participant information sheet (PIS) either via email or post. A consent to contact form will be completed that allows the research team to call the patient to discuss the study further and explore whether they are interested in participating. It is optional and refusal to do so does not in any way affect their usual standard of care. If they complete a consent to contact form, the patient will be given at least 24 hours to read the PIS and discuss with friends and family, to carefully consider their participation in the study.

Participants will also be recruited using advertisements via recruitment posters, leaflets, emails, and social media.

### **7.3.2 Consent**

Only patients with capacity to consent will be considered eligible for the study. If the patient would then like to participate in the study, an informed consent form will be given for them to complete and sign. Should a patient lose capacity during the follow up period, they will be withdrawn from the study. Identifiable data already collected with consent would be retained and potentially used in the study. No further data or samples would be collected or any other research procedures carried out.

For an individual to have capacity to consent they will: understand the purpose and nature of the research; understand what the research involves, its benefits (or lack of benefits), risks and burdens; understand the alternatives to taking part; be able to retain the information long enough to make an effective decision; be able to make a free choice; be capable of making this particular decision at the time it needs to be made (though their capacity may fluctuate, and they may be capable of making some decisions but not others depending on their complexity).

## **8 ETHICAL AND REGULATORY CONSIDERATIONS**

### **8.1 Assessment and management of risk**

#### Disinfecting equipment

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70% ethanol spray will be used to disinfect equipment and will be wiped before and after usage for each participant. Rigorous handwashing will be put in place using alcohol gel to avoid any picking any infections from surface or mouth.

### ActivPAL monitor wear

There is a small risk that the medical grade dressing used to attach the activity monitor to the skin could cause irritation. If this occurs, the participant is encouraged to contact the research team immediately, where an alternative dressing will be provided along with regularly replacing the dressing and cleaning the area. If these methods do not resolve the issue then the participant would be withdrawn from the study.

## **8.2 Research Ethics Committee (REC) and other Regulatory review & reports**

Before the start of the study, a favourable opinion will be sought from the NHS REC.

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- It is the Chief Investigator's responsibility to produce the annual reports as required. The Chief Investigator will notify the REC of the end of the study.
- An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

## **Regulatory Review & Compliance**

Before patients are enrolled into the study, the Chief Investigator will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance. For any amendment to the study, the Chief Investigator, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the

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necessary arrangements in place to implement the amendment to confirm their support for the study as [amended](#).

### **Amendments**

If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor will submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

Amendments will also to be notified to the [national coordinating function of the UK](#) country where the lead NHS R&D office is based and communicated to the participating organisations (R&D office and local research team) departments of participating sites to assess whether the amendment affects the NHS permission for that site.

In all instances the protocol will describe:

- The process for making amendments.
- Who will be responsible for the decision to amend the protocol and for deciding whether an amendment is substantial or non-substantial?
- How substantive changes will be communicated to relevant stakeholders (e.g., REC, R&D, regulatory agencies).
- How the amendment history will be tracked to identify the most recent protocol version.

### **8.3 Peer review**

As this study forms part of a PhD project, it has been reviewed by four academic supervisors.

### **8.4 Patient & Public Involvement**

#### **Cardiac Rehabilitation Team at Bedford Hospital**

Regular meetings will be held between the Bedford Hospital Cardiac Rehabilitation team and the study investigators to discuss how to conduct the study in terms of participant recruitment, data collection and dissemination.

### **8.5 Protocol compliance**

Accidental protocol deviations can happen at any time. If they are to occur, they must be adequately documented and reported to the Chief Investigator and Sponsor immediately.

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Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach. Here, they will also be reported to the NHS REC.

## **8.6 Data protection and patient confidentiality**

All investigators and study site staff will comply with the requirements of the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles, to ensure that patient confidentiality is maintained at all times.

Personal information on source documentation will be filed in a locked cabinet, with only the core research members allowed access. Upon registration to the study, participants will be given a unique participant ID number, which will henceforth be used in all data collection within the study. This will be determined using a number system (Move-01, etc.). A confidential log will be kept by the research team to identify participants with their anonymous ID numbers, which will be encrypted on a secure computer. All other electronic documentation will also be encrypted. Only direct members of the research team will have access to the data, and will be listed on the study's delegation log. Where data is transmitted to sponsors, if necessary, it will only be identifiable by its participant ID number, thus not becoming patient identifiable at any time.

Upon completion of the study, data will be stored for a minimum of 5 years. The data custodian for the Project is Dr Joanna Richards, Senior Lecturer for Clinical Physiology.

## **8.7 Indemnity**

The University of Bedfordshire holds insurance and will provide indemnity to cover relative liabilities associated to this research project. Please see the University of Bedfordshire 'Certificate of Employers Liability Insurance' and 'Professional Indemnity Certificate', which includes insurance cover for research.

## **8.8 Access to the final study dataset**

All members of the research team will have access to the final study dataset. Following publication of the study, access may be available for secondary analysis of the anonymized dataset on reasonable request to the Chief Investigator, which would not be patient identifiable. All patient documentation will reflect the future use of these data in research if necessary.

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## 9 DISSEMINATION POLICY

### 9.1 Dissemination policy

All data arising from the study will be property of the University of Bedfordshire. On completion of the study, the data will be analysed and a final study report prepared. The full study report will be accessible by all, as it will be made publically available. The chief investigator will have the right to publish the final report. Participants will be notified of the outcome of this study by receiving a summary of its findings. Overall, a manuscript will be written for submission to a peer reviewed journal.

### 9.2 Authorship eligibility guidelines and any intended use of professional writers

Authorship will be based on the following 4 criteria, in accordance with the ICMJE:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement 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.

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