The genetics of running-induced injuries involving tendon and bone – epidemiological study

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The genetics of running-induced injuries involving tendon and bone – epidemiological study

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1 Introduction/Background

The purpose of the study is to discover and investigate risk factors for Achilles tendinopathy and bone stress injuries, and to systemise and make this data applicable for a preventive strategy against overuse injuries. Due to the high popularity of running in Australia and relative high incidence of overuse injuries during running, recreational runners were selected as the study group.

Research questions:

1. What is the current incidence of overuse injuries and what are the main contributors to the development of Achilles tendinopathy and bone stress injuries?
2. What are the epidemiological characteristics of recreational runners in Australia and which of them are related to the development of overuse injuries?

An online questionnaire was selected as a method of collecting epidemiological data on Australian runners. The questionnaire was delivered using a commercial online survey software package (SurveyGizmo), which complies with all ethical human research data storage requirements. Test-retest reliability study showed that the survey is reliable and meets the recruitment needs for the project (1). The two main criteria for participation in the survey were that the participants were over the age of 18 and ran a distance of at least 15 km per week. Questions covered demographic characteristics, running habits, history of injuries in the past two years, health status, presence of disorders and chronic conditions, dietary habits, medication and supplement intake and female questions. In order to recruit runners the project is being promoted via mass media, running clubs, fitness clubs and running events.

2 Key papers/theoretical basis for the method


3 Ethical considerations

This protocol has been approved by the Bond University Human Research Ethics Committee (protocol number RO1688B).

This questionnaire-based study involves no major ethical issues. The only ethical consideration is compliance with human research data storage requirements. Please see the Participant Information Sheet (Appendix B) for further detail.
4 Facility and equipment

4.1 Testing facility

Online survey – no physical space requirements.

4.2 Materials

4.2.1 Software

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Photo(description)</th>
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</thead>
<tbody>
<tr>
<td>Boulder, CO 80301 USA</td>
<td></td>
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</tbody>
</table>

5 Training/qualifications/competencies

Please indicate (check the box) to indicate which of the following is required prior to undertaking this method:

Yes  No
☐ ☒ Health and Safety training
☐ ☒ Laboratory induction
☐ ☒ Current First Aid / CPR
☐ ☒ Immunisation
☐ ☒ Method-specific training
☐ ☒ Formal qualification required
☐ ☒ Other specific requirements

6 Restricted access

The use of this method does not require specific qualifications.

7 Health and safety / Risk Assessment

No risk assessments are applicable to this method.
8 Workflow

A survey will be administered online by a platform that allows participants to upload files. Participants will be asked a series of questions encompassing personal details (age, ethnicity, height weight), running information (pace, amount of training, distances, terrain etc), and injury/medical history (type of injury, medical conditions, medications, uploading of medical diagnosis). Data will be collected from all participants who meet the survey inclusion criteria:

- aged 18-50 years,
- running at least 15 km per week.

Survey information will be used for epidemiological analysis and will serve as a database of potential candidates for future studies on injury incidence and prevention.

This survey will be conducted using an online survey platform which allows the participant to upload medical diagnosis files either as a scan or an image taken of the report using a camera phone, for example, to improve accessibility.

8.1 Recruitment plan

Participants will be recruited to complete an online survey using the following methods:

- **Via medical clinics**: Physical Therapy, Radiology and Sports Medicine clinics will be contacted and asked to be involved in the recruitment of participants to the online survey. After making initial contact with the head office/CEO/CMO, the clinic will be provided with flyers directing potential participants to the URL of the online survey. Initial contact will be made via letter, email or in person by the Group Leader. A master list has been created of the major clinics in Australia, their contact details and the person who would be responsible for ‘gatekeeper approval’ for the promotion of the study within the clinic. It is also intended that The Group Leader will utilise an extended network of medical providers. It is anticipated that these clinics will be critical in the recruitment of participants in the ‘injured’ cohorts.

- **Via running races/ events**: Race and event organisers will be contacted initially via email or letter asking to promote the online survey to people who are registering online for the event. Following online registration to an event it is typical that the entrant receives a confirmation email, we would ask that the event organisers include a link to the URL of the online survey in the confirmation email to participants. A master list has been created of the major running events in Australia, the contact details of the organisation holding these events and the person who would be responsible for ‘gatekeeper approval’ for the promotion of the study in association with the event.

- **Advertisements in running magazines and websites**: Advertisements will be placed in running related publications leading potential participants to the URL of the online survey.
• **Social Media:** Social media accounts will be set up for the CRN injury study including Twitter, Facebook and Google + to promote the study and participation to a wider, more general audience. These channels may also be used to cross promote other studies within the CRN and release interesting information, research updates, media articles that are related to the study.

• **Media:** Ad hoc opportunities may arise where the Group Leader is able to promote the study via the media.

Each of the approaches will provide a direct link to the URL of the online survey.

As the inclusion criteria to participate in the online survey is quite broad it is expected that broad-based promotion, such as through social media, event websites and running publications, will be quite effective.

The point of contact for the participants will be a common email address and phone number that will be staffed by the project staff. They will also be responsible for updating, and responding to queries through, social media channels.

Copies of template emails/letters, advertising material can be found in the appendices.

### 8.2 Online survey

#### 8.2.1 Landing page

Once participants follow the link to the survey, they will arrive at the landing page *(Appendix A).*

#### 8.2.2 Participant information

See *Appendix B*. This is what the participant will see if they click on “I wish to see more information about the project” on the landing page.

### 8.3 Data handling and management

Survey responses in SurveyGizmo are exported to Excel. This exports ALL data currently stored in SurveyGizmo, i.e. not just new participants. In Excel, data can be processed and analysed as convenient.

### 8.4 Reporting of information

Participants will not have a written report of results.
## 9 Supplier and ordering information

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<th>Product code</th>
<th>Supplier</th>
<th>Alternative supplier (if applicable)</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
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<td></td>
<td>Company name: SurveyGizmo&lt;br&gt;Name of contact: Seanalee Flaherty&lt;br&gt;Contact details: Email: <a href="mailto:seanalee.flaherty@surveygizmo.com">seanalee.flaherty@surveygizmo.com</a>&lt;br&gt;Web: <a href="http://www.surveygizmo.com">www.surveygizmo.com</a>&lt;br&gt;Phone:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
10 Appendices
10.1 Appendix A: Survey landing page

**Principal Investigator**

xxxx

**Co-Investigators**

xxxx

**Ethics Protocol Number**

xxxx

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Welcome!

- You are invited to take part in this research project if you are:
  - A recreational runner
  - Aged 18 and over
  - Run over 15 km per week
- Please read the Participant Information Form carefully as this will tell you about the research project and explain what is involved. This will help you decide if you want to continue and take part.
- Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or healthcare worker.

**Participation**

- Participation in this study is entirely voluntary.
- You’re not obliged to participate and if you do, you can withdraw at any time without penalty or prejudice.
- To participate, we would like you to complete this online questionnaire, providing details of your medical history, injury history and running habits.
- This survey should take no more than 30 minutes to complete.
- You are able to exit the survey and complete at a later date using the link at the top of the page.
- Your participation, personal details and results will be strictly confidential and only the principal researchers above will have access to this information.

By ticking the ‘I ACCEPT’ option below you are telling us that you:

- understand what you have read;
- consent to take part in the research project;
- consent to participate in the research processes that are described;
- consent to the use of your personal and health information as described;
- understand that you are free to not answer specific items or questions in interviews or questionnaires;
- understand that any data or answers to questions will remain confidential with regard to your identity;
• certify to the best of your knowledge and belief, you have no physical or mental illness or weakness that would increase the risk of participating in this project;
• are participating in this project of your own free will and have not been coerced in any way to participate.

Do you accept to participate in this research study? *This question is required.

- [ ] I ACCEPT the conditions above
- [ ] I DO NOT ACCEPT the conditions above

Further information about the project is available in the Participant Information Form

- [ ] I wish to see more information about the project
10.2 Appendix B: Participant information sheet

What is the purpose of this study?
Identifying new genes or new mutations in known genes will help researchers to better understand the relationship between lifestyle, health status and genetic profile and we hope that this information will ultimately improve health and quality of life, prevent injury or disability, and prevent or treat chronic diseases.

This research is being conducted by xxxx.

What does participation in the research project involve?
Participation in this project involves the completion of an online questionnaire and the agreement to be followed up by a researcher at the Australian Institute of Sport for the provision of a saliva sample for genetic analysis. Not all participants will be followed up to provide a genetic sample.

What will happen to my questionnaire submission?
Your information will be stored in password protected databases. Information about you including medical information that you provide will be treated in such a way that you cannot be identified in publications, except with your permission. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as permitted by law.

What are the possible benefits to participating?
We cannot guarantee that you will receive any benefits from this research, but your participation in the study may help doctors to better understand the relationship between lifestyle, health status and genetic profile with the hope that this will ultimately improve health and quality of life, prevent injury or disability, and prevent or treat chronic diseases.

What are the possible risks to participating in the study?
All medical information is stored in password protected databases. It is possible, though very unlikely, that someone could get access to this database without permission. During the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information and the researcher will discuss whether this new information affects you.

If you become upset or distressed as a result of your participation in the research, the researcher is able to arrange for counselling or other appropriate support. Any counselling or support will be provided by staff who are not members of the research team. In addition, you may prefer to suspend or end your participation in the research if distress occurs.

Can anyone participate in this study?
As long as you meet the criteria specified earlier, you are eligible to take part. The research team have allocated the research funding to areas in which the technology is most likely to find new genes.
Do I have to take part in this research project?
Participation in any research project is voluntary. If you do not wish to take part then you don't have to. If you decide to take part and later change your mind, you are free to withdraw at any stage. All information that you have provided can be destroyed at any time. You can withdraw your consent to participate in this research project by emailing the Principal Investigator at xxxx@xxxx.xx

Before you make a decision to participate in any follow up studies, a member of the research team will contact you so that you can ask any questions you have about the project. You can ask for any information that you want.

How will I be informed of results from of this research project?
In accordance with relevant Australian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information, with which you disagree, be corrected. Please contact one of the researchers named at the end of this document if you would like to access your information.

Is this research project approved?
This project will be carried out according to the National Statement on Ethical Conduct in Research Involving Humans (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The ethical aspects of this research project have been approved by the Bond University Human Research Ethics Committee, protocol number xxxx.

Will I get paid to participate in this study?
You will not be paid for participating in this study.

Who can I contact if I have any questions or problems in relation to this study?
If you wish to discuss further the experimental procedure or have any questions, please do not hesitate to contact xxxx phone (0x) xxxx xxxx or email xxxx@xxxx.xx

If you have any concerns with respect to the conduct of this study, you may contact the Human Research Ethics Committee xxxx on (0x) xxxx xxxx or by email xxxx@xxxx.xx