Plan Overview

A Data Management Plan created using DMPonline

Title: The oral health of elite athletes in Ireland

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Template: 1. UvH template PhD/WP

Project abstract:

The oral health of elite athletes may be compromised by multiple factors associated with their training regime. This study focuses on assessing the diet and oral health of different disciplines of Irish elite athletes at their training centres. Assessment will include a dental examination and a questionnaire related to lifestyle, oral health related behaviours and impact on training and perfomance. Data entry will use KoboToolbox and athletes will use 24-hour dietary recalls and a FFQ using FoodBook24.

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The oral health of elite athletes in Ireland

1. General features of the project

Please fill in the table the table below.

DMP template version number	1.0 (do not change!)
Project number (if available)	10.5281/zenodo.6821564
Name of Research folder on the UvH R: drive	
Name Chairgroup	Elite Athletes Group
Name Chairgroup leader	Michael O'Sullivan
Research group	Michael O'Sullivan, Lewis Winning, Michael Crowe, Annie Hughes, Jo Saele, Sharon Madigan, Aifric O'Sullivan, Brendan Egan
Name data consultant/data steward	Oscar Cassetti
Check date data consultant/data steward	

2. Data collection and re-use

2.1 In collecting data for my project, I will:

Generate new data

This study will involve primary data collection by means of an oral examination, questionnaire and 24 hour dietary recall. This will be an observational cross-sectional study investigating the diet and oral health of Irish elite athletes.

2.2 I will be reusing existing data, and I have the owner's permission for that.

• No, I will not be reusing existing data

Results will be reported based on our data collection and analysis.

$2.3\,$ In collecting new data, will you be collaborating with other parties such as project partners and/ or suppliers of data.

- Yes, I will collect the new data in conjunction with other researchers or research groups
- Yes, we have established user agreements on the rights of the data

Yes, this is a collaborative study involving dentists, nutritionists, a data scientist and a sports physiologist from different Universities/Institutions:

- Trinity College Dublin / Dublin Dental University Hospital
- University College Dublin
- Dublin City University
- Sports Institute Ireland

2.4 What method(s) do you use for the data collection?

• Survey(s)

- Other
- Individual interviews (semi-)structured

KoBoToolbox and FoodBook24 are Software as a Service (SaaS) tools that can record data offline and provide encrypted transfer to cloud storage on databases using Amazon Web Services (AWS).

Customised oral health survey forms were designed using KoBoToolbox/XLS. Data entry was carried out during clinical examination. Athletes self-completed three 24HR using Foodbook24 to produce a nutrient report.

2.5 Check boxes and describe the tools/software you will use for the data collection.

• software for survey research (e.g. Qualtrics)

KoBoToolbox and FoodBook24 are SaaS tools that can record data offline and provide encrypted transfer to cloud storage on databases using Amazon Web Services (AWS). They are both free, open-source and GDPR compliant.

KoBoToolbox is SaaS built on the Xform/ODK standard that provides field data collection, initial analysis and visualisation. KoBoToolbox was used to create a bespoke supplementary dietary behaviours and lifestyle questionnaire, and a clinical examination record based on a modified WHO oral health assessment.

FoodBook24 is a self-completed dietary assessment application that comprises 24-hour dietary recall (24HR) and a food frequency questionnaire.

2.6 Describe what metadata and documentation will accompany the data?

An excel keycode file will be used to pseudonymise participants assigning a random generator number to de-identify participants throughout the study. This number will be inputed to our online data collection forms and used on the consent form. We will include a data dictionary as a centralised repository of metadata.

Only one researcher will have access to the password-protected excel file.

3. Data storage

3.1 Will you store your data at the universities network drive?

No

Data from KoboToolbox and Foodbook24 servers will subsequently be transferred to a password protected .csv file stored on Dublin Dental University Hospital (research server), with access limited to the research team. Once transferred, redundant data on KoboToolbox and FoodBook24 will be deleted. All computers storing data are password-protected. The external hard drive and remotely accessible computer are also encrypted and locked in an office (in the DDUH). Access is restricted to designated staff only.

3.1.a Please indicate:

	Data is collected using the web-based tools described above and will be stored on amazon web services until transferred to password protected .csv file.
be stored	A password protected .csv file stored on Dublin Dental University Hospital (research server), accessible only by research team
be quaranteed	Data will be stored securely via cloud-based software amazon web services until transfer to password-protected .csv file. Access will be protected by storing the information on a password protected computer in a locked office.
	Data will be retained for seven years unless a participant wishes to have their data deleted or removed prior to that.

3.3 Do you need to store non-digital data, e.g. on paper? If so, please describe which data, whether the data are

personal data and who will have access to the data.

The only non-digital data are the consent forms which are paper-based and pseudonymised with the random identifier from the keycode file. These paper forms will be stored in locked filing cabinet at Dublin Dental University Hospital site. Access will be restricted to investigators only.

3.2 Please fill in the table below about which file types you will have and what the format and volume will be. Think about all information that you will have at the end of the project.

File type	Format	Volume
Keycode file	.csv file, google sheets	MB
Statistical data	R/RDS/Rmd files	MB
Data storage	Database (DB) and Simple Storage Service (S3), AWS	МВ

4. Data analysis

4.1 What will be the method by which you will analyse the data?

The diet of elite athletes is associated with an increased risk of dental caries, dental erosion and other oral conditions.

Exploratory data analysis will investigate the 'exposure' of being an elite athlete versus non-elite athlete and also look at differences between different sports disciplines.

Observe the effect of risk factors: dietary factors and lifestlye, training on oral health and performance.

R Markdown/Rstudio files for literate programming and data visualisation.

Exploratory data analysis with emphasis on bayesian approach.

4.2 Which tools will you need to process, analyse or visualise the data?

Other

R programming language to import, clean, join and aggregate the data from the data surveys.

CSV files for remapping/renaming primary survey data prior to import into RDS files.

Initial simple data visualisation using Kobotoolbox and RStudio.

R Markdown files for literate programming, exploratory data analysis, data visualisation.

5. Participants and Personal data

5.1 Does your research involve human subjects?

Yes

Yes, research will involve a convenience sample of 100-150 Irish elite athletes.

- 5.2 Please read the Research Datamanagement Policy outline<u>on this page of the intranet (ENG)</u> or 'Hooflijnen beleid' on this page (NL) of the UvH. Subsequently, check the boxes below.
 - I have read the Research Datamanagement Policy outline and will comply to that

This study has received level II ethical approval from the Faculty of Health Sciences in Trinity College Dublin (TCD). The Data Protection Impact Assessment (DPIA) has also been approved by TCD.

5.3 Give a description of the sample participants and whether they are considered as a vulnerable group.

The sample participants will involve Elite Irish athletes. It will include those competing at professional, olympic, or collegiate levels. This group are potentially vulnerable from an oral health perspective.

5.4 Which personal data are you going to collect? Check the boxes and explain why you need them.

- Contact data full (e.g. address, phone number)
- Contact data limited (e.g. name, email)
- Gender
- Age
- · Racial or ethnic origin
- Experiences (work, education)
- Other

Email: to give participant access to foodbook24

Eircode: to assess deprivation index Gender: to compare males vs females

Age: to assess risk of dental disease in different age cohorts

Experiences: to assess socioeconomic status and it's association to dental disease Ethnicity: to assess risk of dental disease associated with different ethnicities

Other: dental findings

5.5 What legal right do you have to collect the personal data you selected in the question before?

· Informed consent

Informed written consent from each participant for collection of personal data as part of the data collection for the research study.

5.6 Is there, at any time during the research process, a third party handling personal data from your data collection? If so, please give the name of the company, the link to their website and the legal base for processing.

No

5.7 Describe how you will register participants and how you separate personal data from research data.

Participants will be invited to partake in the study by a gate keeper in Sports Institute Ireland. They will be provided with an invitation letter and participant information leaflet at least 7 days prior to meeting the researchers. They will have contact details to contact the researchers about any gueries during this time.

Following a minimum of one week reflection period the gatekeeper will contact potential participants to confirm interest and assign an oral health assessment appointment. Study participants will attend their slot with the investigator. They will have the opportunity to ask any questions prior to signing consent.

6. Information and consent

6.1 Describe how you inform participants and receive their consent to use their personal data.

Participants will be informed via a participant information leaflet and invitation letter. This details the research objections, how their data will be processed and how to contact the research team should they wish.

At least 7 days later, if they have agreed to partake this information will be relayed again, ensuring the participant understands and are willing to be involved. Following this, a written consent form is obtained from each participant.

Participants can contact the researchers at any stage prior to publication to have their data deleted.

6.2 Will participants, parents or guardians receive any reward for participating?

No

This is made clear on the information leaflet and consent form.

6.3 Will the participants, parents or guardians be debriefed at the end of the data collection session or at the end of the project? Please explain.

Yes

Participants will be debriefed at the end of the dental exam highlighting any areas of concern. They will be advised if a visit to their dentist is recommended for further investigations.

7. Privacy and Data Security

7.1 When you deal with large scale, systematic data collections of personal data, you need to do a full Data Protection Impact Assessment (DPIA) to fully describe the mitigations and consult the privacy officer of the UvH. Does this apply for your project?

• Yes

A DPIA was completed and approved by the Data Protection Officer (DPO) in Trinity College Dublin.

7.2 How do you take care of the rights of participants? Please copy the table form the example answer and fill in the third column.

Right of participant	Consideration	Describe how you do it	
Right of access	when a participant wants to know which personal data you collect, in what way will you manage that?	All of the information collected will be fully disclosed to the participant and the reason why explained. It is described in the information leaflet so that it is known to the participant before they agree to be involved in the study.	
Right to rectification	will you manage and how will you let	t Data will be updated and the participant will be informed as such. In case of contact data we contact the person and we will document what has been changed.	
Right to objection	Iwhen a participant objects to use	In the information letter we state that all information that has been collected before the moment of objection, will be kept pseudonymised. The informed consent will also be kept. All personal data in the key file will be destroyed and the person will not be approached any further.	
Right to be forgotten	How do you manage deletion of one's personal data upon request?	Data will be deleted on request and not included in the results.	
What measures do take to protect the privacy of a person?	How do you make sure that the	It will be stored on password-protected computers that are only accessible by the verified researcher.	

8. Data Preservation and Archiving

8.1 What data will be in your data package? Please explain if necessary.

- Documentation of the research process
- Syntaxes, scripts, algorithms
- Description of software
- · Several versions of processed data
- Data documentation

Raw data can not be shared under current ethics approval.

All data analysis will be contained within an R Project folder and include a Readme file which will describe all contents.

8.2 In which repository will the data package be archived and made available for re-use, and under which license?

• I will deposit my data package somewhere else and therefore will contact the datamanagement consultant

The data package will be deposited on Zenodo which will develop a DOI creating a persistent link.

8.3 Give the details of the other repository where you will deposit your data.

Name of the repository	Zenodo
Which persistent identifier	DOI
Which metadata standards	
Which information will be publicly shared	preregistration, DMP, analysis, workflow/research process
Which licenses and permissions are in place	CC BY_NC 4.0

8.4 Upon finishing your project you need to hand over the data package to the UvH, so you need to inform yourself in how to do this. Please read the guidance and check the proper box below.

• I have read the paragraph on Archiving in the Research Data Management Policy and will comply to that

9. Data Sharing

9.1 Describe what re-use of your research data you intend or foresee, and what audience will be interested in your data.

At present, there is no plan to re-use the data.

- 9.2 Are there sharing requirements by third parties? (e.g. funder data sharing policy)? Please explain how you will comply with those requirements.
 - No

9.3 Are there any possible restrictions to data sharing or embargo periods?

We will share our data analysis and auxillary documents but raw data cannot be shared due to the University's ethics application. DOI: 10.5281/zenodo.6821564

9.4 Please state per data type in what way the scientific community will have access to your data.

Data type	Full access	Restricted access	Embargo period	Data immediately linked in the publication	Explanation
metadata	no	no	no	no	not within ethical approval
results	no	yes	no	no	data available on request

10. Costs

10.1 Will you have to hire personnel for the data collection process or any other stage in datamanagement? Please explain and make an estimation.

No

The 2 primary researchers who perform the dental examinations are undergoing a clinical doctorate in prosthodontics and are carrying out this research as part of their thesis submission. There is no salary associated. However, transport costs will be covered by a research budget each student is allocated while undergoing a clinical doctorate in the Dublin Dental University Hospital. The Foodbook24 data will be explained and collected by an undergraduate student associated with the Nutrition department in University College Dublin. This will be a paid role to collect and manage the dietary data.

10.2 Will there be costs for data archiving, e.g. when you work with very large datasets, such as audio and video? Please explain and give an estimation.

No

No, the tools that have been chosen for data collection (FB24 and KBTB) are open source.

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