Plan Overview

A Data Management Plan created using DMPonline

Title: Contemporary twin block appliance wear protocols: A survey of UK orthodontists

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Template: University of Manchester Generic Template

Project abstract:

Functional appliances are a group of orthodontic appliances aimed at growth modification by changing the oral functional environment. Of the wide variety of functional appliances available, the Clark twin block has been found to be the most popular in the UK. The Clark twin block was originally designed to be worn for almost 24 hours daily to maximise all functional forces applied to the dentition, including the forces of mastication. However, patient compliance can be problematic, with functional difficulties alongside perceived negative effects on social interactions. A recent randomised controlled trial which compared part-time and full-time twin block wear protocols showed that both wear protocols resulted in comparable and clinically meaningful dental and skeletal changes. In light of the recent findings of this study, it was felt that a cross-sectional survey of twin block use in the UK would provide important information regarding contemporary trends in wear protocols amongst UK orthodontists.

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Copyright information:

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Contemporary twin block appliance wear protocols: A survey of UK orthodontists

Manchester Data Management Outline

1. Will this project be reviewed by any of the following bodies (please select all that apply)?

- Ethics

2. Is The University of Manchester collaborating with other institutions on this project?

- No - only institution involved

3. What data will you use in this project (please select all that apply)?

- Acquire new data

4. Where will the data be stored and backed-up during the project lifetime?

- University of Manchester Research Data Storage Service (Isilon)

5. If you will be using Research Data Storage, how much storage will you require?

- 1 - 8 TB

6. Are you going to be receiving data from, or sharing data with an external third party?

- Yes

Data are collected via QualtricsXM which is the University's preferred survey tool, as recommended by the Information Governance Office (IGO).

7. How long do you intend to keep your data for after the end of your project (in years)?

- 5 - 10 years

Guidance for questions 8 to 13

Highly restricted information defined in the Information security classification, ownership and secure information handling SOP is information that requires enhanced security as unauthorised disclosure could cause significant harm to individuals or to the University and its ambitions in respect of its purpose, vision and values. This could be: information that is subject to export controls; valuable intellectual property; security sensitive material or research in key industrial fields at particular risk of being targeted by foreign states. See more examples of highly restricted

information.

Personal information, also known as personal data, relates to identifiable living individuals. Personal data is classed as special category personal data if it includes any of the following types of information about an identifiable living individual: racial or ethnic origin; political opinions; religious or similar philosophical beliefs; trade union membership; genetic data; biometric data; health data; sexual life; sexual orientation.

Please note that in line with data protection law (the UK General Data Protection Regulation and Data Protection Act 2018), personal information should only be stored in an identifiable form for as long as is necessary for the project; it should be pseudonymised (partially de-identified) and/or anonymised (completely de—identified) as soon as practically possible. You must obtain the appropriate ethical approval in order to use identifiable personal data.

8. What type of information will you be processing (please select all that apply)?

- No confidential or personal data

9. How do you plan to store, protect and ensure confidentiality of any highly restricted data or personal data (please select all that apply)?

- Not applicable

10. If you are storing personal information (including contact details) will you need to keep it beyond the end of the project?

- Not applicable

11. Will the participants' information (personal and/or sensitive) be shared with or accessed by anyone outside of the University of Manchester?

- Not applicable

12. If you will be sharing personal information outside of the University of Manchester will the individual or organisation you are sharing with be outside the EEA?

- Not applicable

13. Are you planning to use the personal information for future purposes such as research?

- No

14. Who will act as the data custodian for this study, and so be responsible for the information involved?

Dr Ahmed El-Angbawi

15. Please provide the date on which this plan was last reviewed (dd/mm/yyyy).

2021-07-11

Project details

What is the purpose of your research project?

The aims of this research project are:

1. To explore the use of functional appliances in the correction of developing Class II malocclusions in children in contemporary UK orthodontic practice.
2. To investigate Twin block appliance wear protocols prescribed by UK orthodontists.
3. To compare contemporary trends in Twin block appliance use with historical trends.

What policies and guidelines on data management, data sharing, and data security are relevant to your research project?

The University of Manchester Research Data Management Policy
The University of Manchester Data Protection Policy
The University of Manchester Information Governance Office Records Retention Schedule
The University of Manchester Publications Policy
The University of Manchester IT policies and guidelines
The University of Manchester Intellectual Property Policy

Responsibilities and Resources

Who will be responsible for data management?

Queenie Ong (Primary researcher) and Dr Ahmed El-Angbawi (Main researcher)

What resources will you require to deliver your plan?

None

Data Collection

What data will you collect or create?

Data will be collected via an online questionnaire directed at UK orthodontists regarding their routine practice with the use of the twin block appliance. The demographic data collected will only be used to describe the population of orthodontists surveyed. Data are collected and recorded on the QualtricsXM platform. The response data will be exported in CSV file format that can be opened as a spreadsheet in Excel. The response data is unlikely to exceed 8TB.

How will the data be collected or created?

- Survey is currently being validated by a select 10 orthodontists (3 trainees, 4 specialists and 3 consultants) working in a mixture of settings. These 10 orthodontists will be asked to read and complete the questionnaire (word document format), make notes, and provide constructive feedback. The questionnaire is simply exported from Qualtrics in an editable word document format to enable the orthodontists to make notes, comments, and provide feedback. Consideration will be given to the feedback collected from this process in making appropriate amendments prior to finalising the survey. If, as a result of this process, there has been an addition of question(s), or a significant change in phrasing of the questions, the ethics panel will be notified.
- Reliability testing of survey (yet to be tested) will be carried out after survey validation. This process will ideally occur before the survey is disseminated publicly. Reliability testing will be carried out by comparing the responses of a select 20-30 orthodontists at two time points (1 month apart). The orthodontists will be assigned a unique identifier derived using the ‘unique identifiers’ function on Qualtrics. These questionnaires will consist of the exact same questions in the online survey.
- We are in the process of requesting support from the Brisith Orthodontic Society (BOS), for their help in disseminating the finalised

survey to their members' mailing list. This will ensure that only the appropriate population is targeted and will receive a link to the survey

- The survey has been created so that the participant is not allowed to skip questions relevant to them. This is carried out by using the 'force response' function on Qualtrics. This will ensure the collection of meaningful responses

- Documents and data will be organised using the following naming convention:

DocumentTitle_VersionNumber_DDMMYYYY

- Version control will be done through the date recorded and version numbering in the file name. Minor revisions are reflected in the number after the decimal point whereas major revisions are given a new whole number. A version control table will be used to record the revisions and dates of revisions.

- Data and documentation files will be held in separate folders. Data files are further organised according to data type (eg. data collected from validity testing, reliability testing, and main data collection). Documentation files are organised also according to type of documentation file and research activity.

Documentation and Metadata

What documentation and metadata will accompany the data?

1. A protocol which outlines the research question and methodology will be used to guide how the data is collected and analysed

2. Data will be reported in line with the STROBE checklist for cross-sectional studies

3. Documents and data will be organised using the following naming convention:

DocumentTitle_VersionNumber_DDMMYYYY

4. Version control will be done through the date recorded and version numbering in the file name. Minor revisions are reflected in the number after the decimal point whereas major revisions are given a new whole number. A version control table will be used to record the revisions and dates of revisions.

5. Data and documentation files will be held in separate folders. Data files are further organised according to data type (eg. data collected from validity testing, reliability testing, and main data collection). Documentation files are organised also according to type of documentation file and research activity.

6. A summary of supplemental information and metadata will be created as a .txt file will be included in the study data folder to describe:

- Titles and types of the dataset
- Author information
- Date of data collection
- Location of data collection
- Summary of abbreviations
- Contents list of files in dataset
- Relevant relationships between files
- Information about versioning
- Data collection methods
- Quality assurance procedures eg. validity and reliability testing methods

7. The survey captures participants' consent as part of the survey. A question is included in the survey to indicate consent and this will be recorded within the survey response.

8. Individuals selected to form part of the testing panels in the validity and reliability testing processes will receive an invitation to join the panels via email, sent from the researcher's University email. Information regarding the study will be provided, and consent will also be requested as part of this invitation. The individuals will be asked to reply to the email invitation indicating if they accept or decline the invitation, and if they provide their consent. The written replies will be saved as text files within a password protected folder using 7-Zip.

Ethics and Legal Compliance

How will you manage any ethical issues?

- This study has been submitted for Proportionate University Research Ethics Committee (UREC) ethical approval. The application is currently undergoing revision prior to resubmission.

- Participants will be provided with a Participant Information Sheet (PIS), explains the consent process, data protection and confidentiality. The following has been extracted from the PIS to describe the information provided to participants with regards to the aforementioned:

- ***What happens if I do not want to take part or if I change my mind?***

Participation in this research study is voluntary. By completing the survey, you are confirming you have read and understood this Participant Information Sheet and that you give your consent to participate in this study. If you decide to take part you will be asked to tick a box at the start of the survey to confirm your consent. Whist completing the survey, you are free to withdraw at any time by exiting the survey. Your responses will be deleted after 1 week if you do not return to the survey. This also means that you can return and finish an incomplete survey, as long as you return to the survey on the same internet browser on the same mobile device/computer to finish the survey. The survey platform saves your progress by using cookies on your browser. Following completion of the survey, it will not be possible to remove your input from the study as no participant identifiable information is collected and we will not be able to identify your specific input. This does not affect your data protection rights.

- ***What information will you collect about me?***

We do not collect information that could be used to identify you in the survey. All data collected are anonymous. Any unidentifiable general demographic data collected will only be used to describe the characteristics of the participants.

- ***Will my participation in the study be confidential?***

Yes, the survey will be completed anonymously. Additionally, the invitation to participate in the survey is distributed by the British Orthodontic Society via their membership mailing list. This mailing list is not shared with the researchers. Therefore, the researchers do not hold contact information of participants and have no way to identify who has chosen to participate or not.

Data are collected via Qualtrics, which is a University-approved survey hosting software. Data collected in this project will not be shared with anyone not directly related to this research study. All data collected will be stored until 2026 on, after such time the data will be destroyed according to the University of Manchester guidelines in compliance with its Data Protection Policy.

Please also note that individuals from The University of Manchester or regulatory authorities may need review the data collected for auditing and monitoring purposes or in the event of an incident. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

- As mentioned, the survey is completed by participants anonymously, and no personal details are captured during the survey. The researchers will not hold the participants' contact information, as the survey link will be disseminated by the BOS via their mailing list.

- Individuals involved in validity testing will be emailed (from the researchers via a University email account) the survey (in word document) which will contain a unique identifier. The individuals will provide feedback by returning the document via email. The individual's name, contact details and unique identifier will be tabulated on a password protected excel spreadsheet. This will conceal the individual's identity when analysing the feedback provided, but still enable researchers to trace and contact the individuals involved should further clarity be required as part of validity testing. The password protected spreadsheet will be stored in a separate folder from the feedback data received.

- Individuals involved in reliability testing will be assigned a unique identifier derived using the ‘unique identifiers’ function on Qualtrics. This unique identifier will conceal individuals identities but allow for responses to be compared between time points.

How will you manage copyright and Intellectual Property Rights (IPR) issues?

The University of Manchester will own the copyright of data collected. The data collected is not intended for reuse. The data may be presented at academic conferences or published in peer reviewed scientific journals.

Storage and backup

How will the data be stored and backed up?

The University of Manchester's Research Data Storage (RDS) will be used to store the master copy of all data and documents, and back-ups. The main investigator/supervisor will apply for space on RDS.

How will you manage access and security?

- Data will be stored on the RDS. Files stored on this service can be considered secure. The default type of storage allocated is said to be *replicated* and *snapped*: these storage *shares* can be considered “backed up” – each file is held in two data-centres and if damaged or deleted by accident, can be recovered for up to 35 days.

- Access to data storage will be carried out on campus. Any off-campus access will be carried out via the University VPN.

- The data collected in this study is anonymous and non-confidential. The excel spreadsheet containing the contacts of individuals involved in validity testing will be encrypted using the Microsoft encryption function. The plain text files of written consent gained from individuals involved in validity and reliability testing will be stored in a password protected folder using 7-Zip. These items will be stored in separate folders from the survey data collected.

- No paper records will be generated or collected as part of this survey.

Selection and Preservation

Which data should be retained, shared, and/or preserved?

All documentation created and data collected from the survey with be retained for 5 years after publication, which is the minimum default period set according to The University of Manchester Information Governance Office Records Retention Schedule.

What is the long-term preservation plan for the dataset?

The Research Data Storage will be used for the long term preservation of data (5 years) as my supervisor will remain at the University for this period of time and will have continued access to the service.

Data Sharing

How will you share the data?

Data collected in this project will not be shared with anyone not directly related to this research study. However, the survey results may be shared with the BOS and presented at academic conferences or published in peer reviewed scientific journals.

Are any restrictions on data sharing required?

- The results shared with the BOS and presented at conferences or published in peer reviewed scientific journals will not reveal the identities of participants. This information is relayed to participants within the PIS. The following has been extracted from the PIS to describe the information provided to participants with regards to the aforementioned:

- ***Will the outcomes of the research be published?***

The study is part of an MSc project associated with the University of Manchester. The survey results may be shared with the British Orthodontic Society (BOS) and presented at academic conferences and/or published in peer reviewed scientific journals. These results will not reveal the identities of participants.

- Participants are asked to read the PIS which outlines how their data will be shared. This will be reiterated twice: In the invitation email, and on the first page of the survey. Participants are informed in the PIS that by completing the survey, they are confirming that they have read and understood the PIS and that they provide consent to participate in the study. This consent is checked again at the start of the survey by ticking a box.
- Participants are also informed in the PIS that following completion of the survey, it will not be possible to remove their input from the study as no participant identifiable information is collected and we will not be able to identify their specific input.