**Participant Information Sheet and Consent Form**



**Study Title**

Digital-powered healthcare: Improving communication, engagement and treatment compliance in patients with implant-related infections

**Version 1.1: March 2023**

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**Investigators:** Dr. William Steadman, Dr. Beat Schmutz, Prof. Michael Schuetz, Prof. Uwe Dulleck, Dr. Stephen Whyte, Dr. Paul Chapman, Prof. Kevin Tetsworth, Ms. Bonnie Woods, Dr. Jason Brown, Mr. Shannon Dias, Mr. Brett Droder, Mr. Philip Andrews, Dr. Arpita Das, Mr. Tim Cudmore, Dr. Julie Vermeir.

**Location:** Royal Brisbane and Women’s Hospital (RBWH)



**1. Introduction**

You have been referred to the mDRIFT (multidisciplinary Device Related InFection Team) clinic at the Royal Brisbane and Women’s Hospital (RBWH) because you have orthopaedic implant or trauma related infection. You are invited to participate in this clinical trial. It will be tested by patients with orthopaedic implant or trauma related infections treated at RBWH, and our goal is to expand its use to others with equally complex conditions requiring ongoing multidisciplinary care.

We understand that this must be a distressing time for you. It is important, however, that you understand what this study entails so that you can make an informed decision about whether you wish to continue participating.

This Participant Information Sheet/Consent Form tells you about the research study. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask the nurse any questions about anything that you do not understand or want to know more about. Participation in this research is voluntary. If you do not wish to take part, you do not have to. Whether you decide take part, or not, you will receive the best possible medical care.

If you decide that you want to take part in the research study, you will be asked to sign the consent section. By signing it you are telling us that you:

* Understand what you have read
* Consent to take part in the research study
* Consent to the tests and research that are described
* Consent to the use of your personal and health information as described.
* You will be given a copy of this Participant Information and Consent Form to keep.

**2. What is the purpose of this research?**

Patients like yourself with orthopaedic implant or trauma related infection belong to a complex population. Many live out of the MNHHS catchment with no local access to the expertise required for their complex needs.

The mDRIFT was set up in 2020 by the Jamieson Trauma Institute (JTI) at RBWH to help combat this difficult clinical complication through effective coordination of patient care.

The purpose of this study is to evaluate a new dynamic communication pathway utilising a low-cost mobile app framework as a new way to facilitate two-way communication between clinicians and patients. Some patients will use a wearable consumer fitness tracker connected to the mobile app.

This study will enable researchers to determine the effectiveness of mobile app communication platform, with and without fitness tracker, in improving communication, engagement and treatment compliance in patients with implant or trauma related infections. The results of the current study will provide valuable information regarding the feasibility of doing a larger clinical trial using this mobile communication app to assist the management and care of patients like yourself.

**3. What does participation in this research involve?**

You will be participating in a randomised controlled research project. You will be randomly assigned into one of the following groups. To try to make sure the groups are the same, each participant is put into a group by chance (random). The results will then be compared between groups. There are no additional costs associated with participating in this research project. If you agree to participate in this study, you will be asked to sign the consent form and to participate in a consultation session with one of the research team members, that will take up to 15 minutes of your time on four occasions, coinciding with your standard clinical appointments, over three months.

At the beginning of the study, you will receive a $25 gift card for compensating your time for the first appointment and taking part of this study. Also, at the end of the study, you will receive an additional $50 gift card for travel, parking or other expenses.

Besides, if you are allocated in Group A or B, when you complete the assigned questionnaire and achieve a set goal related to your care, treatment, health care journey and recover, a fun-based reward system will generate special badges and/or encouraging messages.

***Group A (App only)***

If you are allocated in this group, a team member will help you to download the mDRIFT mobile App (Android or iOS) on your smartphone. You will also receive instruction to use the App. At home, you will need to use your Wi-Fi or mobile Internet access to complete the survey and any communication with your mDRIFT clinicians.

***Group B (App + Wearable device)***

If you are allocated in this group, you will receive a Bluetooth enabled wearable fitness tracker (Mi Smart Band 7) and a team member will help you to download the mDRIFT mobile App (Android or iOS), Zepp Life App (Android or iOS) and Google Fit App (Android or iOS) on your smartphone. A team member will also help you to connect the fitness tracker to these three Apps. You will also receive instructions to use these three Apps and the wearable device. At home, you will need to use your Wi-Fi or mobile Internet access to complete the survey, any communication with your mDRIFT clinicians and updating GoogleFit/mDRIFT App.

***Group C (Control)***

If you are allocated in this group, one of our research team members will ask you to complete some traditional paper-based surveys, summarised in the next section.

**4. What do I have to do?**
 ***Group A (App only)***

If you agree to participate in this study, during your routine mDRIFT clinic appointments at baseline, week-2, week-6, and 3-month, one of our research team members will ask you to complete the following surveys using your mDRIFT mobile app –

* + Your knowledge, skill and confidence to manage your health and health care (Patient Activation Measure, PAM 13)
	+ Your experiences of treatment and care (Australian Hospital Patient Experience Question Set, AHPEQS)
	+ Your health-related questionnaire (EQ-5D-3L).
	+ Additionally, you will receive pop-up notifications via the mDRIFT mobile App on your smartphone to record perceived pain on a scale from 0 (no pain) to 100 (worst pain) each week.

***Group B (App + Wearable device)***

Same as Group A.

In addition, our team member will also train you to use the Mi Smart Band. This band will be used to record your vitals, including heart rate, resting heart rate, sleep duration, steps, distance travelled and energy expenditure. You will be asked to charge the Band every three to four days. You will also be asked to open the Zepp Life and Google Fit Apps every day (preferably, or at least every two to three days) so that the app can automatically update the above-mentioned vitals.

***Group C (Control)***

If you agree to participate in this study, during your routine mDRIFT clinic appointments at baseline, week-2, week-6, and 3-month, one of our research team members will ask you to complete the following traditional paper-based surveys

* + Your pain score (Visual Analogue Scale)
	+ Your knowledge, skill and confidence to manage your health and health care (Patient Activation Measure, PAM 13)
	+ Your experiences of treatment and care (Australian Hospital Patient Experience Question Set, AHPEQS)
	+ Your health-related questionnaire (EQ-5D-3L)

**5. Other relevant information about the research study**

This study is being conducted at mDRIFT clinic and aims to recruit up to 48 patients with orthopaedic implant or trauma related infection.

**6. Do I have to take part in this research study?**

Participation in any research study is voluntary. If you do not wish to take part, you do not have to do so. If you decide to take part but change your mind at a later stage, you are free to withdraw from the study at any point in time.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with RBWH.

**7. What are the possible benefits of taking part?**

***Group A (App only)***

The information from the mDRIFT mobile App will help you understand your progress, track your care journey, treatment plan, self-monitoring and direct contact with your clinicians. You will also be able to view your progress in graphical and tabular form. You will also receive educational content related to your health condition.

Your response will increase your doctor’s understanding of your healthcare journey, injury and recovery. The information from this study could help patients with implant or trauma related infections improve their care and health outcomes. This research will help healthcare professionals understand and make decisions regarding the management of these injuries.

**Group B *(App + Wearable device)***

Same as Group A. Additionally, at the end of the study, you will be able to keep the Smart Band 7.

***Group C (Control)***

There is unlikely to be a direct benefit to you from your participation in this research. However, your response is very important as it will provide control data for evaluating the effectiveness of the mobile app in improving the patient-clinician communication for patients with implant or trauma related infections. This research will help healthcare professionals understand and make decisions regarding the management of these injuries.

**8. What are the possible risks and disadvantages of taking part?**

There no risk associated to take part of this project.

The questionnaire we are taking are for research purposes. They are not intended to be used for a clinical examination. The purpose of these questions is not to diagnose, treat or manage your injury. Research team will look at your responses for features relevant to the research study.

The Mi Smart Band 7 stores your activity and sleep data, measured by its sensors, on an internal non-removable memory chip. The stored data is accessed by the Zepp Life App on your smart phone via Bluetooth connection. While Bluetooth data transfer is encrypted and only works within a short distance of 10 meters (30 feet), like all wireless technology it is not hack proof. To minimise any risks, do not accept Bluetooth connection requests from unknown sources; and turn Bluetooth off when in public places.

Zepp Life is committed to ensuring that your personal information is protected and will take all practical measures to protect your personal information. However, it should be noted that the use of the Internet is not entirely secure, and for this reason Zepp Life cannot guarantee the security or integrity of any personal information they process. In addition, as you access your account, you may choose to use a two-step verification process for greater safety. When you send or receive data from your device to the Zepp Life servers, they ensure it is coded. All your personal information will be stored on secure servers that are protected in controlled facilities. Files and records containing your personal information will be kept in Zepp Life’s offices and/or on their servers or their service providers.

Google Fit data will be stored and backed up securely on Google cloud servers from Google. Google data centres are protected with several layers of security to prevent any unauthorized access.

The mDRIFT app uses the PEP Health communication platform, which is certified (ISO27001) to meet Australian data and security standards. In addition, the platform has been assessed by the Queensland eHealth Cyber Security Group to meet their standards. Your data on the mDRIFT app and clinical dashboard will be stored encrypted on a secure server in Australia.

**9. What will happen to my information?**

By signing the consent form, you give the research team permission to collect, use and disclose information from your medical records for the purpose of this research study. Any information obtained in connection with this research project that can identify you will remain confidential. Information may include:

* Your age, sex, postcode, cultural background, employment status
* The cause and details of your injury
* Details about surgery you undergo for this injury (if applicable)
* Date of hospitalisation and discharge
* Duration of your hospitalisation
* If you admitted to ICU
* Clinical examination results
* Blood test results (e.g., inflammatory markers)
* Photos you have taken of your wound (if applicable). We will ensure that you cannot be identified from any photo used for research or publication.

As a participant, you will be assigned a unique study number (USI). Only this number will be used to identify you in all study records. There will be a confidential record (accessible only to designated study staff unless required by law) kept linking your name to your USI will be kept on secure computer servers and/or in a locked filing cabinet in a locked office.

The study involves the storage of information that may be used in future research with your consent. Your data will be available for access by other researchers in a format that cannot identify you. By signing the Consent Form, you authorise release of, or access to, this information to the relevant researchers. All Personal Identifiable Information will be coded and only available for you and your clinicians. All form/questionnaire/survey results will be extracted from the mobile app, will be stored under the unique identifier in a secure data lake after deleting the Personal Identifiable Information. Your details, journey data, and submitted form results will be stored in accordance with the Australian Privacy Act 1988, health data guidelines recommended by the Office of the Australian Information Commissioner (OAIC).

All the information collected from you will be stored as non-identifiable data in Metro North secure servers and systems in secure, password-protected databases. All non-electronic data will be stored in a locked filing cabinet in a secure office.

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

Regulations in Australia require all research-related data and hospital medical records to be kept for a minimum of 15 years. Your records will be kept for that period and may then be disposed of in line with contemporary data disposal systems.

**10. Can I withdraw from this study?**

You can withdraw from the study at any time by contacting a member of the research team (contact details are listed below). You will be asked to complete and sign the ‘Participant Withdrawal of Consent Form’ provided at the end of this document.

If you wish to withdraw from the study, there will be some options –

1. You will be able to choose to disconnect from the mDRIFT app. This will allow you to keep mDRIFT app on your mobile but stop recording your data to the dashboard. However, you will still be connected to the health care team.
2. Alternatively, you can delete the mDRIFT app from your mobile.
3. If you do not want to use the previously collected mDRIFT app data, you may request a copy and to delete the collected data from the system. The research team will proceed immediately.
4. You can request Zepp Life to remove your data from their server/system.
5. You can remove an activity from your Google Fit history. You can also delete data tied to your Google Fit account. When the data is deleted, it disappears forever.
6. You can permanently delete all your data on the Mi Smart Band 7 by performing a Factory Reset.

**11. What happens when the study ends?**

We expect the results of the study to be published in a medical journal and shared at scientific and medical conferences. If you would like these to be made available to you, please inform a member of the research team of this.



**12. Who is organising and funding the research?**

This research is an investigator-led study conducted by RBWH, Queensland University of Technology as well as the Jamieson Trauma Institute (JTI). Queensland University of Technology and the RBWH with the generous support of the Study, Education and Research Trust Account (SERTA) Advisory Committee, the RBWH Foundation, and Liquid State have contributed funding for trial in this study and could benefit from the outcomes of the research but will not receive any personal information.

**13. Who has reviewed the research study?**

All research in Australia involving humans is reviewed by an independent group of suitably qualified individuals who form part of a Human Research Ethics Committee (HREC). This study has been reviewed and approved by the RBWH Human Research Ethics Committee.

This study is carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

**14. Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

* If you require further information regarding this study, please contact JTI
Phone 07 3646 3929
Email: jamieson\_trauma\_institute@health.qld.gov.au
or
Bonnie Woods

Email: Bonnie.Woods@health.qld.gov.au

* If you have any comments or complaints about the conduct of this study, please contact either JTI (as above), or the reviewing HREC who approved this research:

**Reviewing HREC approving this research and HREC Executive Officer details**

|  |  |
| --- | --- |
| Reviewing HREC name | Metro North Health HREC A |
| Telephone | 07 3646 5280 |
| Email | MetroNorthResearch-Ethics@health.qld.gov.au |

**Complaints contact person**

|  |  |
| --- | --- |
| Position | MNHHS Research Governance Manager |
| Telephone | 07 3647 9550 |
| Email | MetroNorthResearch-RGO@health.qld.gov.au |

Should you suffer any injuries or complications as a result of this research study, you should contact JTI and/or a member of the research team as soon as possible and you will be assisted with arranging appropriate medical treatment and care. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

**Screening Form for Group A** *(Adult providing own consent)*

**Study Title:**
Digital-powered healthcare: Improving communication, engagement and treatment compliance

in patients with implant-related infections

**Please read the following and place a tick (✓) to the answers that apply to you:**

|  |  |  |
| --- | --- | --- |
| **Statement** | **Yes** | **No** |
| I am over 18 years old |  |  |
| I have internet WiFi access at home |  |  |
| I use a smartphone |  |  |
| I am prepared to install the mDRIFT patient App on my smartphone |  |  |
| I am able to attend my routine mDRIFT clinic appointments (baseline, week-2, week-6, 3 month) at the RBWH  |  |  |

**Screening Form for Group B** *(Adult providing own consent)*

**Study Title:**
Digital-powered healthcare: Improving communication, engagement and treatment compliance

in patients with implant-related infections

**Please read the following and place a tick (✓) to the answers that apply to you:**

|  |  |  |
| --- | --- | --- |
| **Statement** | **Yes** | **No** |
| I am over 18 years old |  |  |
| I have internet WiFi access at home |  |  |
| I use a smartphone |  |  |
| I am prepared to install the mDRIFT patient App on my smartphone |  |  |
| I am prepared to wear and use the Xiaomi Smart Band 7 activity tracking device |  |  |
| I am prepared to install the Zepp Life App on my smartphone |  |  |
| I am prepared to use my Google Fit App/Apple Health App, or install Google Fit App (Android or iOS) on my smartphone for this study |  |  |
| I am able to attend my routine mDRIFT clinic appointments (baseline, week-2, week-6, 3 month) at the RBWH |  |  |

**Screening Form for Group C** *(Adult providing own consent)*

**Study Title:**
Digital-powered healthcare: Improving communication, engagement and treatment compliance

in patients with implant-related infections

**Please read the following and place a tick (✓) to the answers that apply to you:**

|  |  |  |
| --- | --- | --- |
| **Statement** | **Yes** | **No** |
| I am over 18 years old |  |  |
| I am able to attend my routine mDRIFT clinic appointments (baseline, week-2, week-6, 3 month) at the RBWH |  |  |

**Consent Form (***Adult providing own consent)*

**Study Title:**
Digital-powered healthcare: Improving communication, engagement and treatment compliance

in patients with implant-related infections

|  |  |
| --- | --- |
| **Principal Investigator and Contact Details:**Dr William SteadmanEmail: William.Steadman@health.qld.gov.au | **Contact person:** Bonnie Woods Email: Bonnie.Woods@health.qld.gov.au |

**Investigators:** Dr. William Steadman, Dr. Beat Schmutz, Prof. Michael Schuetz, Prof. Uwe Dulleck, Dr. Stephen Whyte, Dr. Paul Chapman, Prof. Kevin Tetsworth, Ms. Bonnie Woods, Dr. Jason Brown, Mr. Shannon Dias, Mr. Brett Droder, Mr. Philip Andrews, Dr. Arpita Das, Mr. Tim Cudmore, Dr. Julie Vermeir.

**Location:** Royal Brisbane and Women’s Hospital (RBWH)

Declaration by participant

- I have read the Participant Information Sheet, or it was read to me in a language that I understand.

- I understand the purposes, procedures and risks of the research described in the study.

- I understand that neither I nor my family will receive financial benefit from the outcomes of the Research described above.

- I have had an opportunity to ask questions and I am satisfied with the answers I have received.

- I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

- I understand that I will be given a signed copy of this document to keep.

|  |
| --- |
|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature: |  |  Date:  |  |  |
|  |

**c** I also agree that the de-identified research data, which has been collect about me in this study, can be used for other future research projects related to this topic area without contacting me.

|  |
| --- |
|  |
|  |
|  | Signature: |  |  Date:  |  |  |
|  |

**Declaration by Study Doctor/Senior Researcher/Delegate†**

I have given a verbal explanation of the research study; its procedures and risks and I believe that the participant has understood that explanation.

|  |
| --- |
|  |
|  | Name of Study Doctor/Principal Investigator/Delegate† (please print) |  |  |
|  |  |
|  | Signature: |  | Date |  |  |
|  |

† A senior member of the research team must provide the explanation of, and information concerning, the research study.

**Note: All parties signing the consent section must date their own signature.**

**Withdrawal of Consent Form**

**Study Title:**
Digital-powered healthcare: Improving communication, engagement and treatment compliance

in patients with implant-related infections

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| --- | --- |
| **Principal Investigator and Contact Details:**Dr William SteadmanEmail: William.Steadman@health.qld.gov.au | **Contact person:**Bonnie Woods Email: Bonnie.Woods@health.qld.gov.au |

**Investigators:** Dr. William Steadman, Dr. Beat Schmutz, Prof. Michael Schuetz, Prof. Uwe Dulleck, Dr. Stephen Whyte, Dr. Paul Chapman, Prof. Kevin Tetsworth, Ms. Bonnie Woods, Dr. Jason Brown, Mr. Shannon Dias, Mr. Brett Droder, Mr. Philip Andrews, Dr. Arpita Das, Mr. Tim Cudmore, Dr. Julie Vermeir.

**Location:** Royal Brisbane and Women’s Hospital (RBWH)

I wish to WITHDRAW my participation in the study effective from the date below.
I request that the study handles the information they have collected about me in the following way:
(**choose ONE option ONLY**)

**c** DESTROY all information collected about me so it can no longer be used for research.

**c** RETAIN all information collected about me so it can continue to be used for research.

I understand that:

- No further information about me will be collected for the study from the withdrawal date.

- Information about me that has already been analysed and/or included in a publication by the study may not be able to be destroyed.

- Choosing to withdraw from the study will not affect my access to Health Services or Government benefits.

|  |
| --- |
|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature: |  |  Date:  |  |  |
|  |

Please email a copy of this form to:

jamieson\_trauma\_institute@health.qld.gov.au

Alternatively, please post the form to:

Dr. Arpita Das

Jamieson Trauma Institute

Level 11, Block 7, Royal Brisbane and Women’s Hospital

Herston, QLD 4029