Patient Information Leaflet

Study title Self-Injection Education by Digital Clinicians- A Feasibility Randomised Controlled Trial

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Principal investigator's title: Professor

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Data Controller's/joint Controller's Identity **Self-Injection Education by Digital Doctors and Nurses- A Randomised Controlled Trial**

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You are being invited to take part in a research study to be carried out at University Hospital Galway in Health Education by **Digital Healthcare Professional Avatar** – A Study Project Team, NUIG.

Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends, or GP (doctor). Take time to ask questions – don't feel rushed and don't feel under pressure to make a quick decision.

You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

You don't have to take part in this study. If you decide not to take part, it won't affect your future medical care.

You can change your mind about taking part in the study any time you like. Even if the study has started, you can still opt out. You don't have to give us a reason. If you do opt out, rest assured it won't affect the quality of treatment you get in the future.**Why is this study being done?**

This research study is taking place to determine the feasibility and acceptability of using **digital representations of doctors and nurses with pre-programmed and approved knowledge** to enhance patient's education.

The study will be conducted on patients, and health care professionals to get their feedback and perspectives on the use and feasibility of **digital healthcare professionals (HCPs)**.

Who is organising and funding this study?

Self-Injection Education by Digital Doctors and Nurses- A Randomised Controlled Non-Inferiority Trial is a project run out of Professor Derek O'Keeffe's HIVE lab in National University of Ireland Galway.

Self-Injection Education by Digital Doctors and Nurses- A Randomised Controlled Non-Inferiority Trial has been granted funding to conduct this research. We receive no payment to recruit patients to this study.

Why am I being asked to take part?

Any patients in the Bariatric Clinic, UHG who are being started on semaglutide are being invited to participate in the research study.

It is important to include all key stakeholders for feedback into the platforms to make improvements for the users.

How will the study be carried out?

This study is starting from May 1st, 2022, to July 31st, 2021. This study will take place in Diabetes Day Care Centre, UHG and National University of Ireland Galway (NUIG).

Approximately 55 other patients will participate for this research.

All participants of the study will be asked to fill out a short questionnaire before using the **Digital HCP** platform and six weeks after. The first questionnaire will take place today in the clinic. The follow-up questionnaire will be emailed to you in 6 weeks and will also be accompanied by a phone call from one of our doctors or nurses here in the clinic.

We may also invite you to interview to explore in more detail the acceptability and feasibility of the proposed technology as well as potential barriers in using the **Digital Doctor** by offering any comments at this point and by rating the feasibility on a scale from 1 to 100.

What will happen to me if I agree to take part?

You will be assigned to one of two groups. One group will use the **Digital HCP** before a consultation with the healthcare professional. The second group will visit the healthcare professional for education as normal. You will be assigned to either group at random.

This study may require you to use and assess the **Digital HCP** and provide your feedback in the Questionnaire. You will assess your own attitudes towards injections in the questionnaires also and have the chance to report any side effects after 6 weeks. This will require a maximum of 15 minutes today and 10 minutes in 6 weeks time.

Questionnaire records?

Participants will be assigned a study number and or a pseudonym, respectively. The master list of participants' names with numeric identifiers and/or pseudonyms will be stored securely away from all other data with access only to the PI, project manager and members of the research team, who are subject to NUIG data protection and security policies and procedures. Participants will be informed that no data will be published in such a way as to identify individuals.

This data will only be used for research and Technology assessment purpose, with no intention to damage or bring distress to data subject.

What other treatments are available to me?

This research study does not impact or change treatment or medical care given to you by your clinical care team. If you choose not to participate, all the services will continue, and nothing will change.

What are the benefits?

There are no personal benefits in taking part in this study.

This study will enable us to study and conduct research on enhancing **digitalisation** used for education. Your feedback will provide important information to improve on current and future technologies.

What are the risks?

There is ***NO*** risk in taking part in this study. We only require your feedback on new attitudes to injections and new technology.

What if something goes wrong when I'm taking part in this study

It is your choice whether to participate or not. You can discontinue in taking part in this study at any point. If in case, you need any kind of assistance Co- investigators will be more than happy to help. If you are unwell or feeling uncomfortable at any point you can communicate it to Co- investigators.

Will it cost me anything to take part?

This study will ***not cost*** you any expenses. It only requires 15 minutes of your time to fill out the Questionnaires and interact with the **Digital HCP**.

Is the study confidential?

We won't contact your GP or any other healthcare provider, your medical records are not required for this research. Only the BMI recorded today at the clinic by the HCP will be included to help randomly assign patients to their group. No samples will be collected from you.

The information you share will be kept securely in line with NUI Galway Policies and Procedures, and your privacy will be protected. Copies of applicable policies are available for review at: https://www.nuigalway.ie/data-protection/policiesandprocedures/ and https://www.nuigalway.ie/information-solutions-services/ictpolicies/

Participation is completely voluntary, and you can withdraw at any time without any effect on your care. Any information from the study, be it in reports or publications, will be presented in a way that ensures you will not be identifiable.

This information will be kept in strictest confidence and will be stored in a locked filing cabinet. Information about you stored on a computer will be encrypted and password protected with access available only to the research team, who are subject to NUI Galway Data Protection and Security Policies and Procedures.

What will be done with my information?

The answers you give to the questions on the questionnaires will be put into a computer and examined. it. Any identifiable remarks you might make during the questionnaire will be removed before we analyse it.

Data Protection

We will use your age, gender, BMI and Questionnaire score to assign you to a group. No identifying information will be used.

Legitimate interests' interest and for scientific research purposes only– see Article 6 and 9 of the General Data Protection Regulation 2016. If uncertain contact the Data Protection Officer.

The Questionnaire data will only be accessed by **Digital HCP** team (NUIG) for the purposes of this study.

As per the Data Protection Act and NUIG policy and procedure the data will be kept in strictest confidence and records linking study participants ID with identifying features will be stored in a locked filing cabinet in the researcher's (PI) workplace in NUIG during the study period. All data stored on a computer will be encrypted and password protected with access available only to the PI project manager and research team. As per NUIG policy and procedure the data will be stored for five years on NUIG secure and approved IT system after which the data will be destroyed.

No risk to the data subject. Only name, phone numbers and email addresses will be obtained from patients who are willing to take participate. Other data is confined to that concerning the study only- which will be anonymous and not in the public domain. This data will only be used for research and Technology assessment purpose, with no intension to damage or bring distress to data subject.

Participants will be asked to use and assess the **Digital HCP and** provide feedback and comments through a written survey. At any point they can withdraw consent by informing the Co- Investigators.

Yes, data subjects have a right to lodge a complaint with the Data Protection Commissioner.

Yes, the data subjects have a right to request access to their data and a copy of it.

Yes, data subjects have a right to restrict or object to processing.

Yes, data subjects have a right to have any inaccurate information about them corrected or deleted.

Yes, data subjects have a right to have their personal data deleted.

Yes, data subjects have a right to data portability.

No, there be no automated decision making, including profiling.

Yes, the data subjects have a right to object to automated processing including profiling if they wish.

No personal data will be processed further.

No data will be transferred outside the country.

Where can I get further information?

If you have any further questions about the study or if you want to opt out of the study, you can rest assured it won't affect the quality of treatment you get in the future. If you need any further information now or at any time in the future, please contact:

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