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A comparison between patient obesity self-injection education using artificial-intelligence powered "clinicians" and humans

Submission date
13/08/2024

Recruitment status
No longer recruiting

Registration date
15/08/2024

Overall study status
Completed

Last Edited
28/10/2024

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
An assessment of how knowledgeable, confident, capable and satisfied patients are after learning how to inject themselves with and oversubscribed and under available weight loss medication from an AI-powered avatar, similar to chat GPT, compared to a trained human.

Artificial Intelligence, namely automated chatbots, are a new invention that may offer a role in healthcare communications. Other AI applications have already been shown to be as intelligent as doctors need to be to pass their exams and efficient at making diagnoses. They may offer scalable solutions, in a time of worldwide healthcare worker shortages. Some studies suggest up to 50% of continental regions are eligible for semaglutide treatment- while very few have access to assessment or the education provided to use it.

Other AI applications have already been shown to be as intelligent as doctors need to be to pass their exams and are efficient at making diagnoses.

However, using AI interventions may incorporate trade-offs in patient satisfaction, personalisation and trust. We aimed to assess where these trade-offs lie, and primarily if an AI chatbot, custom-made had the ability to educate humans on how to use once-weekly semaglutide injections.

Who can participate?
Patients starting semaglutide self-injection administration, for the first time and awaiting education

What does the study involve?
Participating in the study involves providing the research team with anonymised baseline information about your age, BMI, race and education level. Baseline measurement includes assessment of participants knowledge of self-injection and their new medication in a 4 question custom-made test. Self-efficacy of self-injection is also measured. Participants are then assigned to receive their education from a human clinician, or from a bespoke artificial intelligence avatar

programme, with generative-like text capacity, audio, video and emotional response technology designed solely for the purpose of this study. Allocation is at random, and out of the control of participants and researchers. At this point, participants receive their education which takes 10-15 minutes in their assigned way and are assessed by the practice nurse for safe discharge to the community to use their new medication. After being assessed as safe, the participants complete a final test of their knowledge, and surveys on satisfaction, trust, and attitudes towards future use of this technology. Two weeks after enrollment, participants are contacted over the phone to assess self-efficacy after real-world use of their injections using a validated measure. The results of the outcome measures are then compared between both groups. Both groups are free to gain access to the "digital clinician" after follow up.

What are the possible benefits and risks of participating?
Benefits may include access to a novel technology and active inclusion in the progression of healthcare, with an opportunity to contribute your opinion on the use of such technologies- negative or positives. There is a risk involved in the loss of continuity of care with the obesity specialist nurse in the clinic, if assigned to use the "digital clinician". This risk was minimised by ensuring all participants were seen by the practice nurse after completing their participation in the study, and that they were phoned again in 2 weeks by a human for follow-up on their course.

Where is the study run from?
University Hospital Galway (Ireland)

When is the study starting and how long is it expected to run for?
October 2022 to July 2023

Who is funding the study?
University Hospital Galway (Ireland)

Who is the main contact?
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Contact information

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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers
Nil known

Study information

Scientific Title
OBESITY medication self-injection education using “Digital Clinicians”: a feasibility randomised controlled trial

Study objectives
AI-powered "Digital Clinicians" in the form of AI-powered avatars are comparable to human clinicians at teaching patients how to inject medications for the treatment of obesity

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/03/2023, Galway Clinical Research Ethics Committee (Room 2, 2nd floor, HR Building, Merlin Park Hospital, Galway University Hospitals, Galway, H91N973, Ireland; +353 91775022; colette.collins@hse.ie), ref: C.A 2920

Study design

A single-centre feasibility randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See outputs table

Health condition(s) or problem(s) studied
Overweight and Obesity

Interventions
Patients starting semaglutide once weekly self-administered injections for the treatment of overweight and obesity were invited to partake in the study. Participants were randomised to reveive their mandatory education on self-injection from an AI-powered "digital clinician" (intervention group) or from an Obesity Specialist Nurse (control group)- the current standard of care. Randomisation by minimsation was used- a deterministic process which precludes allocation concealment by assigning individuals to their study group one-by-one as they enter the study. Participants are assigned to the group that minimises differences between the groups across pre-determined baseline variables- in this case BMI, age, pre-study knowledge of semaglutide, and pre-study self-efficacy with injections were measured before the intervention, and allocation was determined.
Primary and secondary outcomes included self-efficacy, knowledge, trust in your healthcare provider and consultation satisfaction which were measured using questionnaires in both groups immediately after education provision, under supervision from a member of the research team.

Intervention Type
Behavioural

Primary outcome measure
Self-Efficacy with injections, measured 2 weeks post-education session.
Measured using "post" section of the validated "Self Injection Assessment Questionnaire"

Secondary outcome measures
1. Knowledge of Semaglutide use- Custom-made 12 Question Test. Measured immediately after Education session- Day 0
2. Trust in the healthcare provider- Jian et al. Trust in Healthcare provider scale (modified). Measured immediately after Education session- Day 0
3. Consultation Satisfaction- Patients' Overall Satisfaction with Primary Care Physicians Scale (Modified). Measured immediately after Education session- Day 0
4. Usability.-Telehealth Usability Questionnaire (Modified)- Measured immediately after Education session- Day 0

Overall study start date
01/10/2022

Completion date
01/07/2023

Eligibility

Key inclusion criteria
1. Starting semaglutide self-injection administration, for the first time and awaiting education
2. Capacity to give consent to being involved in the study
3. Judged to be capable to provide self-administration of injections by the human clinicians in the clinic- this will be determined in advance of being referred for education
4. There are no age limitations but patients will typically be over the age 18, as the research will take part in an Adult Outpatient Department Clinic. Inclusion will be based on an assessment of capacity rather than age

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
56

Total final enrolment
56

Key exclusion criteria
1. Critically ill patients, who do not have capacity to consent or participate in the surveys due to their medical status (will be determined by the clinical care team)
2. While patients diagnosed with dementia or cognitive impairment will not be automatically excluded, participants must be able to give fully informed consent and can participate in completing the survey

Date of first enrolment
01/05/2023

Date of final enrolment
01/07/2023

Locations

Countries of recruitment
Ireland

Study participating centre
University Hospital Galway
Newcastle Rd, Galway, H91 YR71
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Sponsor information

Organisation
University Hospital Galway

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
https://www.saolta.ie/hospital/university-hospital-galway

ROR
https://ror.org/04scgfz75

Funder(s)

Funder type
University/education

Funder Name
University of Galway

Alternative Name(s)
Coláiste na hOllscoile, Gaillimh, Ollscoil na hÉireann Gaillimh, Queen's College, Galway, University College, Galway, NUI Galway, National University of Ireland, Galway, National University of Ireland Galway, Ollscoil na Gaillimhe, National University of Ireland, Galway/NUI Galway, NUI Galway, OÉ Gaillimh

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Ireland

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/10/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from seancoleman@live.ie, upon publication of the data. It will be available for as long as the research team see that it adds value to the public domain. All data will be anonymised, as was discussed with study participants. Data access will be permitted to those who provide a name, email address, location and reason for wishing to access the data, on condition of only sharing/disseminating it with permission in an agreed fashion.
Raw data may be added to a public repository in the future.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			15/08/2024	No	Yes
Protocol file			15/08/2024	No	No