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Co-designing a device to guide breathing instructions during deep inspiration breath-hold (DIBH) radiation therapy (RT) for service users with hearing impairments

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Abstract

Introduction: This study aims to investigate the key characteristics of a device to support patients with hearing impairments in utilising deep inspiration breath-hold (DIBH) radiation therapy (RT).

Method: A qualitative approach was adopted. Semi-structured interviews were conducted both online and in person with 11 participants, including key stakeholders from a range of backgrounds: radiation oncologists, radiation therapists, medical physicists, RT service managers, industry vendors, and deaf service users. Data were analysed using thematic analysis, following the six-step approach outlined by Braun and Clarke.

Results: Participants' attitudes towards a device were explored across four key themes:

- Device characteristics
- Shape and size
- Interference with treatment
- Associated challenges

Thematic analysis identified several unifying themes, including the importance of co-designing a device incorporating both vibrational and visual elements. Overall, participants expressed a preference for a small and wireless device.

Conclusion: This study identified potential characteristics for a device to support patients with hearing impairments in accessing DIBH during their radiation therapy treatment. A device incorporating both visual and vibrational elements may be optimal for addressing the diverse needs of patients in this cohort.

Introduction

Currently, adjuvant radiation therapy (RT) is the standard of care for patients with breast cancer, following breast-conserving surgery or mastectomy.[1] Loco-regional control and overall survival are increased with RT.[1] However, there are associated radiation-induced toxicities. Radiation-induced heart disease (RIHD) arises frequently due to coronary and capillary vessel damage.[2] The damage induces a progressive fibrotic process, which leads to changes to circulatory mechanisms and thus, may induce fatal ischaemic heart diseases (IHD).[3] Motion management techniques like deep inspiration breath-hold (DIBH) reduce the mean heart dose up to 3.4 Gy when compared to free breathing treatment.[4] This is equivalent to a 13.6% reduction in the anticipated risk of cardiac disease.[4] The use of DIBH in the treatment of left breast cancer can also reduce the dose to the left anterior descending coronary artery and the left lung.[5] In Ireland, the National Cancer Control Programme recommend DIBH for cardiac-sparing for patients with left breast cancer.[6] DIBH may also be used for some patients having radiation therapy for thoracic lymphoma and lung cancer.[7,8]

DIBH requires the patient to breathe in and hold their breath for a defined length of time whilst radiation is delivered.[9] This facilitates lung inflation, which, during the treatment of left breast cancer, displaces the heart away from the treatment field and consequently reduces the mean cardiac dose.[9] DIBH can be delivered using various techniques, including active breathing control and voluntary DIBH techniques, such as monitoring the patient's surface using Surface Guided Radiation Therapy (SGRT) or a device.[10–12] Voluntary DIBH systems have visual systems that deliver real-time feedback to patients on their breathing patterns.[11,13] Feedback systems initially depend on the guidance of Radiation Therapists (RTTs), whereby the RTTs

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instruct the patient when to breathe in, hold and when to breathe out. In the context of DIBH, patients with hearing impairments may have difficulty hearing verbal prompts communicated via intercom systems. In the absence of these systems, patients with hearing impairments may not be suitable candidates for DIBH. As a result, patients in this cohort may not be receiving evidence-based treatment that could decrease their risk of cardiac toxicities. Currently, there is no standardised approach to address this challenge within radiation therapy practice.

Pre-intervention surveys have reported that adults who are deaf have statistically significantly lower baseline scores for cancer-specific knowledge and are at a higher risk of not understanding cancer-specific screening tests compared with the average expected health literacy of hearing peers.[14] Evidence of outcomes for deaf cancer patients is scant.[14] Therefore, it is vital that adapted care is provided to patients who have hearing impairments.[15]

There are several assistive devices available in the market for people who have hearing impairments. This includes assistive listening devices (ALDs), which amplify sounds and can be used with a hearing aid or cochlear implant. Augmentative and alternative communication (AAC) devices can range from a simple animated table to a computer generator that synthesises speech from text. AAC devices are used to enable people with communication disorders to communicate. Alerting devices are also available that connect to an alarm, for example, a blinking light emits to alert someone of an event happening.[16] Novel visual devices, including virtual reality, have also been investigated specifically in the context of DIBH.[13,17] Currently, there is no device available to assist patients who have hearing impairments in accessing DIBH, and this research aims to address this gap.

This research aims to qualitatively explore the perspectives of service users (SUs), medical professionals, and industry representatives' opinions on the development of a device that assists patients who have hearing impairments in accessing DIBH RT. Specifically, the study aims to:

- Identify preferred device characteristics
- Explore perceived challenges to device implementation in clinical practice

Methods

Study design

A qualitative study design using semi-structured interviews was conducted to identify perspectives on the ideal characteristics of a device to support patients with hearing impairments undergoing DIBH RT.

Participants and recruitment

Participants ($n = 11$) included both medical professionals and SUs, who were interviewed and recruited across Ireland using a purposive sampling strategy to ensure representation of relevant stakeholders.

The sample included two deaf SUs, two RTTs, two medical physicists (MPs), two radiation oncologists (ROs), two RT service managers (RTSMs), and one SGRT vendor (V) representative. SUs were recruited through the Cork Deaf Association, and medical professionals were recruited online with the assistance of the research team. All participants met the inclusion criteria outlined in Table 1.

Table 1. Study inclusion and exclusion criteria

Inclusion	Exclusion
SUs and medical professionals over the age of 18.	SUs and medical professionals under the age of 18.
SUs who are deaf or have hearing impairments.	Medical professionals who have less than three years' experience with DIBH and SGRT.
Medical professionals who have experience with DIBH and SGRT.	–

Participants received information leaflets and provided written informed consent before the interview. Leaflets contained resources on DIBH and SGRT. Participants were invited to attend interviews online or in person. Online interviews were conducted via Teams (Microsoft Corp, Redmond, WA) and video recorded. In-person interviews were audio recorded. A sign language interpreter attended the SUs interviews.

Data collection

Semi-structured interviews were conducted using a predefined interview guide developed in line with the study's aims and informed by the research team's clinical experience. (see supplementary material). The audio was transcribed by a researcher, and any identifying information of participants was removed. Each interview lasted approximately 30 minutes. The interviews were transcribed verbatim by a researcher, and any identifiable information was removed to ensure confidentiality.

This study adhered to the consolidated criteria on reporting qualitative research (COREQ).[18]

Data analysis

Thematic analysis was completed by adhering to a systematic, verifiable, and continuous sequential format.[19] The transcribed interviews were read repeatedly by the primary researcher. This familiarity facilitated clustering of data to form codes. These codes were then grouped to identify emerging themes.[20] Themes were reviewed iteratively in relation to both the coded extracts and the full transcripts to ensure internal coherence. Credibility was enhanced through analytic discussions within the research team. This analysis followed Braun and Clarke's reflexive thematic analysis approach.[20] Interviews continued until ongoing analysis indicated no new themes were being generated.

Results

Participants' perspectives were analysed using thematic analysis, from which four main themes were identified: device characteristics, shape/size of device, interference with the treatment, and potential challenges. The quotations were edited minimally for readability.

An overview of the themes and subthemes identified is presented in Figure 1 with supporting participant quotations in Table 2.

Themes

Device characteristics

All participants expressed a preference for a small and wireless device, emphasising the importance of portability and ease of use

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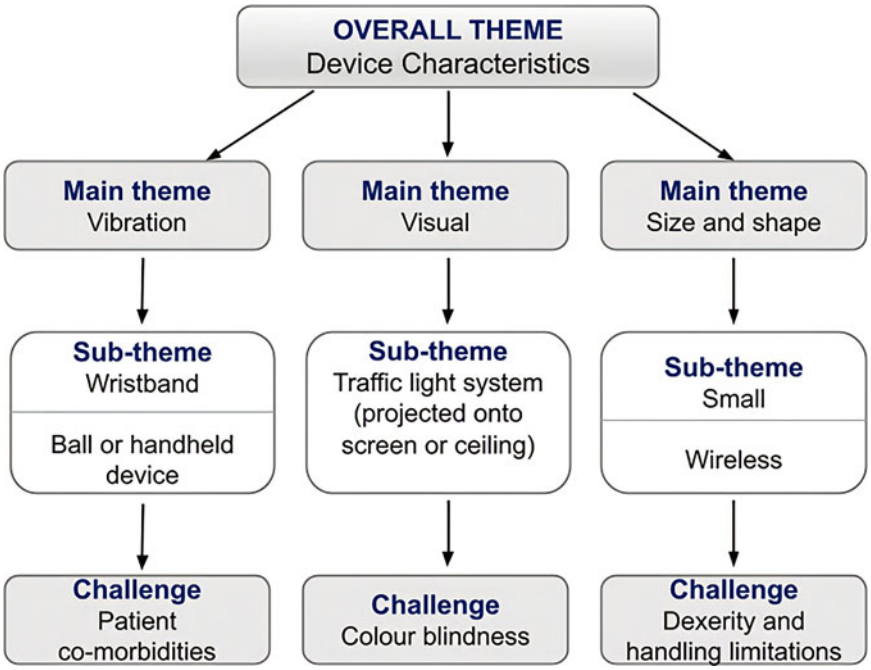

Figure 1. Overview of the overall theme, main themes, subthemes, and associated challenges relating to device characteristics.

in a clinical setting. Smaller devices were deemed to be less intrusive and more practical, particularly in departments where space and time are both limited. In comparison, larger devices were viewed as potentially overwhelming for both patients and staff, as they may increase the complexity of the procedure and may require additional handling. Participants also expressed that more compact designs could reduce disruptions to the current clinical workflow.

Vibration

Six participants (MP2, RT1, RO2, RTSM1, SU2, and V) favoured both a vibrational and visual device to adhere to patient preferences and co-morbidities.

One of the SUs preferred a wristband-type device in which different vibrations mean different commands.

> *"So, the first one could be "tick tick tick", pause which would be "hold" and then a "zzzzushhhh" vibration could be to breathe out." – (SU2)*

Visual

Five participants preferred a visual-only device (MP1, RO1, RT2, RTSM2, SU1). A traffic light system was commonly suggested as a mechanism for delivering instructions.

RTSM1 discussed the idea of creating a digital application (app) for patients. This would allow the RTTs to pre-record educational videos explaining DIBH. The videos could incorporate subtitles and be further delivered by a deaf presenter. The app was described as potentially being very useful for patient education. However, the additional functionality of guiding breathing instructions live would have to be implemented.

The SUs highlighted the importance of involving a deaf interpreter, noting that communication needs vary depending on literacy levels, language preferences and familiarity with Irish Sign Language (ISL).

> *"You might have a deaf person, for example, who has been home all the time, and they might have their own home signs, or a deaf elderly person who uses their own signs. There's a lot of reasons why a person may not have access to mainstream signing. Or you might have a person who has come from a different country who doesn't sign ISL yet. So, if a hearing interpreter were to sign ISL to them, they wouldn't understand it. So that's when you would bring in the deaf interpreter." – (SU1)*

One of the SUs also suggested a visual device with a countdown timer, which could be either projected on the ceiling or appear on a small screen along with subtitles.

> *"If you had a countdown system that might be better, so they'll know when they'll be coming to the end of their breathing. That would be better than just a traffic light system." – (SU1)*

Interference with the treatment beam

All the medical professionals emphasised that any device should not interfere with the treatment beam or SGRT. Suggested solutions included a screen with a visual display placed above the patient's face or a wearable vibrational device, such as a wristband.

Potential challenges of the device

Participants mentioned several advantages and disadvantages associated with both visual and vibrational devices. The MPs, RO1 and RTSM2 noted that vibrational signals could startle patients, which may cause movement and therefore require repositioning. Additionally, the MPs and RO1 mentioned that some patients may not sense the vibration as strongly because they have peripheral neuropathy, arthritis, or other co-morbidities.

During the interviews, participants agreed that instructing the patient to breathe in more or less would be challenging to implement into a traffic light system. As a result, participants suggested introducing a vibrational element to combat this challenge.

Discussion

To date, this is the first known study to investigate the potential for device development to support the delivery of DIBH for deaf SUs. The findings highlight important gaps in accessibility within radiation therapy practice and reinforce the need for effective and inclusive communication. Hill et al reported three unifying health

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Table 2. Themes, subthemes, and selected quotes which emerged from the semi-structured interviews

Theme and subthemes	Quotes
Device characteristics	"Something really, really small, that is, controlled from outside in some easy way. Ideally with some sort of Bluetooth or Wi-Fi where you're not relying on wires that need people to get over" – (RTSM1) "You might even consider something like an app" –(RTSM1)
	"Anything like our visual aid at the moment, which is basically an iPhone. So that size." – (RT2) "You could go for like an air tag type size attached to a strap" – (V)
Vibrating device	"I definitely think something vibrating would be good because I think some patients want to keep their eyes closed when they have treatment." – (V) "Maybe even a ball in your hand or something? Then you know there's no vision involved. They can have their eyes closed." – (MP2) "So, you'd have to have like a key. One short one, one long one and if they can vibrate to different strengths and mean different things." – (RT1) "Even like a wristband to wear and send a pulse through. When the left hand vibrates breathe in, when the right hand vibrates breathe out something like that." – (SU2)
Visual device	"For a simplistic device I like the idea of a traffic system, maybe something fixed to the end of the bed so they can see." – (MP1) "I think the traffic light system is very good, it's very visual. I don't see that could be an issue for a deaf patient." – (RO2)
Interference with treatment beam	"For example, if you were scanning a breast and it was somewhere down on the leg that would be totally fine. If it was out of the treatment field that would be okay." – (MP1)
Challenges	"If patients are going to be on Taxol prior to radiotherapy, they could have peripheral neuropathies. So that could impact how they can sense vibration." – (RO1) "A vibrating system could be good, but it could get confusing because how would you know what means what? It would definitely be overwhelming in the first place because is it one vibration to breathe in? Two for hold? So that wouldn't be as clear." – (SU1) "I've seen in CT where they say, "we need you to breathe a bit more" or "we need you to breathe less" So, it would be better to have more than "Stop" and "Go" but that would get complicated." – (MP1) "I suppose the fear would be something that vibrates in someone's pocket, they might give a little jump and then, you've disrupted their positioning." – (RTSM2) "Even if it's out of the beam, potentially if it was RF based it might cause some issues." – (MP2) "I would say no to VR goggles, just purely based on feedback that we have. One of the SGRT providers does give the option of goggles, and usually it isn't very well accepted by patients. Infection control usually have a lot to say about it as well, unfortunately" – (V)

CT, Computed Tomography; RF, radiofrequency; VR, virtual reality; SGRT, surface guided radiation therapy.

care barriers experienced by deaf patients. This includes poor health literacy, limited access to health care resources and inadequate linguistic and cultural competency among clinicians.[14] These barriers are reflected in this study, particularly the communication challenges that arise during techniques such as DIBH. Effective communication is an integral component of this study, and it is essential that health care providers adapt their communication to align with the needs of all patients.

A key finding of this study was the preference for a small, wireless, and user-friendly device. Patients undergoing DIBH must concentrate on their deep breathing; therefore, introducing large devices with complexities may compromise compliance. Studies on workflow optimisation have shown that simplification and standardisation improve efficiency, safety, and overall patient experience.[21] Therefore, introducing complexities into the treatment may negatively impact both patient compliance and treatment delivery, highlighting the need for minimally disruptive devices. Any device developed to aid in DIBH delivery should integrate into the clinical workflow without causing additional strain for the patient or the clinicians.

Additionally, visual guidance systems were preferred, including subtitles and pre-recorded instructional videos created by a deaf presenter, communicating the entire process to patients and when to take a breath in or out. A study by Saby *et al.* reported that several radiation therapy departments in the United Kingdom continue to rely only on verbal instructions when delivering DIBH, despite this being inadequate for patients with hearing impairments.[22] The limited use of visual aids identified in their study reinforces the requirement for additional devices, such as those proposed by participants in this study. Of note, visual countdown timers, as suggested by a participant, would not be suitable given treatment delivery variables such as dose rate. Further limitations of visual devices include patients with additional visual impairments, further highlighting that a single modality approach is not sufficient.

A vibrational feedback device was also a proposed solution for this cohort. In the radiation therapy department where patients are unable to maintain visual focus during DIBH, vibrational cues offer a practical and inclusive approach. Participants suggested that different vibrational strengths, amplitudes, and different locations of the vibration could be used as a key to mean different commands. This further demonstrates the feasibility of developing a non-verbal DIBH communication system. For example, participants mentioned that if the patient had a wristband on each hand, a vibration on the left could mean breathe in, and a vibration on the right could mean breathe out.

Importantly, combining both a visual and vibrational system reflects the needs and preferences of the patient. Offering patients a choice between these two systems based on their unique needs and desires may increase engagement and compliance. Patient-centred care is essential in oncology decision-making. This promotes a stronger bond and an increased trust between the patient and their health care provider.[23] This suggests that radiation therapy departments should incorporate multimodal communication strategies rather than a single standardised approach.

Under Article 25 of the United Nations Convention on the Rights of Persons with Disabilities (UNCRPD), Ireland has committed to ensuring that people with disabilities have access to

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the same range, quality, and standard of free or affordable health services as others.[24] However, the findings of this study, in addition to those of Saby *et al.*, suggest that this standard is not consistently met in radiation therapy practice.[22] The absence of accessible communication methods may result in deaf patients being excluded from receiving advanced treatment techniques like DIBH, highlighting the importance of bridging the gap between policy and clinical implementation.

Patients should not be disadvantaged in accessing treatment techniques due to their hearing impairment. Currently, there is no standardised approach to delivering DIBH to this patient group. The development of a suitable device could facilitate access to DIBH and improve dosimetric outcomes compared with free breathing treatment plans.

Limitations of this study included a relatively small sample size, with a low number of SUs ($n = 2/11$). However, several similar issues raised by both SUs and professionals within the themes identified suggest that the findings are meaningful and warrant further exploration. Furthermore, there are very limited studies published that compare the treatment outcomes between patients who are deaf and their hearing peers in radiation therapy. This limited the ability to contextualise these findings within a broader evidence base. Another limitation of the study was that the coding of these data was not verified independently, and the interview guide was not piloted. Future studies should aim to include additional SUs and medical professionals to support product development and implementation of practical solutions, for example, medical engineers and linear accelerator vendors.

Conclusion

This study highlighted key characteristics of a device to support patients with hearing impairments in accessing DIBH as part of their radiation therapy treatment. Participants consistently favoured a small and wireless device, emphasising the importance of minimising disruption during treatment.

The findings suggested that a device incorporating both visual and vibrational elements may offer a flexible and inclusive approach to addressing the needs and preferences of this patient cohort. Such multimodal strategies may help to overcome limitations associated with relying on single modal approaches like verbal instructions during DIBH.

The absence of accessible communication strategies may contribute to inequities in DIBH delivery, known to reduce cardiac dose in radiation therapy. Improving communication methods and exploring the inclusion of assistive technologies into current radiation therapy workflows may improve both patient experience, treatment delivery, and optimisation.

These findings should be interpreted with caution due to the exploratory nature of the study and relatively small sample size. Further research is required to assess the design, development, and implementation of a device and to determine its feasibility and effectiveness in clinical practice.

Supplementary material. To view supplementary material for this article, please visit https://doi.org/10.1017/S1460396926100454.

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Competing interests. The authors declare no conflict of interest.

Ethical standards. The authors assert that all procedures contributing to this work comply with the Helsinki Declaration of 1975, as revised in 2008, and have been approved by the institutional committee (Medical School Social Research Ethics Committee, University College Cork).

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