Original Paper

Iterative Patient Testing of a Stimuli-Responsive Swallowing Activity Sensor to Promote Extended User Engagement During the First Year After Radiation: Multiphase Remote and In-Person Observational Cohort Study

Abstract

Background: Frequent, sensor-assisted monitoring of changes in swallowing function may help improve the detection of radiation-associated dysphagia before it becomes permanent. Although our group has prototyped an epidermal strain and surface electromyography sensor that can detect minute changes in swallowing muscle movement, it is unknown whether patients with head and neck cancer would be willing to wear such a device at home after radiation for several months.

Objective: We aimed to iteratively assess patients' design preferences and perceived barriers to the long-term use of the prototype sensor.

Methods: In study 1, we administered a questionnaire about a hypothetical throat sensor. Survivors of pharyngeal cancer who received treatment 3 to 5 ago and were part of a larger prospective study were asked about their design preferences for a hypothetical throat sensor and rate their willingness to use the sensor at home during the first year after radiation. In studies 2 and 3, iterative user testing was conducted. Patients with or survivors of head and neck cancer attending visits at MD Anderson's Head and Neck Center were recruited for 2 rounds of on-throat testing of prototype sensors while completing a series of swallowing tasks. Afterward, participants were asked about their willingness to use the sensor during the first year after radiation treatment; in study 2, patients also rated the sensor's ease of use and comfort, whereas in study 3, preferences were elicited regarding haptic feedback.

Results: The majority of respondents in study 1 (116/138, 84.1%) were willing to wear the sensor for 9 months after radiation, and participant willingness rates were similar between studies 2 (10/14, 71%) and 3 (12/14, 86%). The most prevalent reasons for participant unwillingness were that 9 months seemed excessive, there was an unwanted increase in responsibility, and they felt self-conscious. Across all 3 studies, the sensor's ability to detect developing dysphagia increased willingness the most compared with its appearance and ability to increase adherence to preventive speech pathology exercises. Direct haptic signaling was also rated highly, particularly for indicating correct sensor placement and swallowing exercise performance.

Conclusions: Patients and survivors were receptive to the idea of wearing a personalized risk sensor for an extended period during the first year after radiation, although this may have been limited to well-educated, non-Hispanic participants. Among the unwilling, there were significant concerns with various aspects of the sensor's burden and appearance.

Trial Registration: ClinicalTrials.gov NCT03010150

Keywords

user-centered design; patients with head and neck cancer; dysphagia throat sensor

Introduction

Background

In 2021, approximately 32,000 Americans developed laryngeal or pharyngeal cancer, both of which have a 5-year survival rate of 61% for all stages combined [1]. The management of these cancers often includes high-dose intensity-modulated radiation therapy designed to spare pharyngeal muscles and reduce the incidence of radiation-associated dysphagia (swallowing difficulty) [2]. However, a range of studies have reported that approximately 60% of patients who received intensity-modulated radiation therapy developed long-term swallowing problems within 2 years after radiation ended, ranging in intensity from inability to swallow solid food without compensatory strategies to being completely feeding tube dependent [3-10].

As with most chronic conditions, early detection and intensive swallowing therapies are key to preventing long-term dysphagia [11-26], especially if patients are adherent to swallowing therapy instructions [27]. However, noninvasive screening procedures for the early detection of radiation-associated fibrosis do not yet exist in the United States. Instead, gold-standard modified barium swallow test and fiberoptic endoscopic evaluation of swallowing are typically ordered after the patient begins to complain of difficulties with swallowing [12]. Furthermore, preventive swallowing therapies are not always prescribed before the development of radiation-associated dysphagia [28-30]. Unfortunately, once radiation-associated dysphagia is clinically detected, there is little hope for fully restoring normal function [11,31,32].

To detect radiation-associated dysphagia before it becomes permanent, it is necessary to monitor changes in swallowing function much more frequently than currently possible in the clinical setting. Providing patients with personalized feedback regarding dysphagia risk or subclinical changes in swallowing activity could be done in the clinic during standard surveillance visits, but increasing the periodicity of these visits would increase patient burden by requiring more frequent travel to the medical center for swallowing imaging and tests. Frequent, at-home monitoring with wearable sensors between scheduled surveillance visits could address this gap in monitoring, especially if the sensors were designed to support decision-making regarding the initiation of intensive speech language therapies [33]. To this end, researchers have developed a myriad of devices that can be worn on the skin and measure a range of mechanical, optical, biochemical, electrical, and acoustic signals with high fidelity [34-39].

However, sensor performance alone is not sufficient for improving health outcomes, as patient engagement is also important [40]. Within the specific context of ameliorating dysphagia in survivors of head and neck cancer, repeated at-home monitoring over a period of months, if not years, is necessary to demonstrate a clinical advantage over the current treatment paradigms. Unfortunately, most mobile technologies fail to engage patients over sustained durations, with most mobile health (mHealth) interventions for chronic disease reporting

steep declines in use, some as high as 95% within the first few weeks, depending on the technology and context [41-43]. The most frequently cited reasons for discontinued use are decreased interest in the technology after its novelty abates, perceived lack of usefulness relative to burden, poor user experience with the technology, and frustration with technical issues [44-47].

To counter these barriers, it is widely agreed that user-centered testing should be conducted in a sustained and iterative fashion during the design and development of new health technologies. User-centered testing assesses the human-technology interface by evaluating how well the technology incorporates into end users' daily routines, habits, and capabilities, known loosely as user acceptability [40,48]. Beyond acceptability, technologies should also be designed such that their potential to effect changes in patients' attitudes and health behaviors is maximized. The persuasive system design model developed by Oinas-Kukkonen and Harjumaa [49] describes 4 categories of persuasive design principles that optimize the likelihood of health behavior change: task support (personalized design features that make it easier for users to achieve their goals), social support (leveraging interpersonal learning, eg, via web-based community forums), dialog support (providing feedback to users in a manner that helps them move toward their goal, eg, with praise and rewards), and system credibility (the perceived clinical expertise embedded within the sensor output). User-centered testing is conducted during the development of relatively few mHealth interventions, which may be one of the reasons for diminishing patient engagement and eventual abandonment [50-53]. In the US market, the user abandonment rate of fitness trackers is 50% within the first 6 to 12 months of use [44,54]. Abandonment rates are higher among patients aged ≥70 years: a study found that 43% of their sample had abandoned their sleep and activity trackers within the first 2 weeks of use [55].

A recent review of 51 mHealth intervention studies targeting chronic diabetes and cardiovascular or pulmonary diseases noted that diminished patient engagement was prevalent and posed a significant threat to the effective use of the technology. Accordingly, nonsignificant effects on clinical markers outweighed significant findings in a 2:1 ratio [42]. Therefore, our study explicitly addressed the design of a wearable sensor in terms of its future use for home-based assessment for 9 months, starting with the 3rd month after radiation to the 12th month. All design preferences and opinions were solicited within the context of sustaining engagement with the sensor for 9 months during the first year after radiation, as repeated measurements over time would be needed to detect patterns of developing dysphagia in patients whose treatment has ended.

Goal of This Study

We conducted an assessment with patients with or survivors of head and neck cancer to determine their needs and preferred characteristics regarding the design of a wearable sensor to deliver personalized risk of dysphagia. Specifically, we assessed the perceived barriers to wearing the sensor for 9 months and impact of the proposed design features on willingness to wear the sensor for 9 months, starting at the 3rd month after the end of radiation treatment (to allow for healing from radiation skin burn) until the 12th month after treatment. In the first of 3 iterative user-centered tests, we surveyed a large cohort of survivors of head and neck cancer who

were receiving treatment for the past 3 to 5 years to assess the perceived need for the sensor and desired design features for future prototypes. In study 2, we assessed user acceptability for a wired prototype sensor within a small sample of long-term survivors, oversampled for radiation-associated dysphagia. Finally, in the third user test, we tested a revised prototype on a second sample of patients with head and neck cancer undergoing active treatment to obtain a better sense of competing priorities during a fraught time in their lives. The revised prototype included more elastic and comfortable materials for the strain sensor and custom-made dry electromyography sensors, as opposed to commercial sensors. During the third test, we repeated our questions about user acceptability and willingness to wear the sensor for 9 months and asked new questions about bidirectional feedback in the form of haptic (vibration) signaling.

Methods

Study 1

Design and Eligibility

Survivors of head and neck cancer who were already enrolled in a psychosocial parent study were asked to answer a questionnaire about a hypothetical throat sensor. Men and women were eligible for the parent study if they (1) had received radiation with curative intent for oropharyngeal (stage II-IVb), laryngeal (II-IVb), hypopharyngeal (I-IVb), or nasopharyngeal cancer (I-IVb) or for an unknown primary cancer with cervical metastases; (2) had received treatment at least 2 years ago; (3) were aged at least 18 years; and (4) spoke English. Men and women were excluded if they (1) had received treatment for previous head and neck cancer; (2) had a history of previous head and neck surgery (previous biopsy, tonsillectomy, and tracheotomy were allowed); (3) had other cancer diagnoses, except for nonmelanoma skin cancer; or (4) had a history of current oropharyngeal dysphagia unrelated to cancer diagnosis (eg, dysphagia due to an underlying neurogenic disorder).

Recruitment and Data Collection Procedures

For the psychosocial parent study, all eligible patients were approached for recruitment at the radiation clinic's radiation education class after being identified at the weekly multidisciplinary tumor board conference. The accrual rate for entry into the original parent study was 77%, and demographic and disease information was collected at baseline. Patients who were already enrolled in the psychosocial parent study and were still alive (234/234, 100%) were contacted via phone to determine whether they would answer optional questions about a hypothetical sensor to be worn on the throat. Patients who did not return calls after 5 attempts or without working phone numbers were not approached further for enrollment in study 1. After providing informed consent, participants completed the optional questionnaire administered via REDCap (Research Electronic Data Capture; Vanderbilt University), telephone, or mail at a single time point [56]. For mailed questionnaires, a research staff person's phone number was provided if the patient had any questions about the questionnaire.

Measures

Overview

Demographic information regarding age, race, ethnicity, employment, income, and marital status was obtained using a questionnaire. The disease stage was abstracted from the medical record. The participants then completed a questionnaire assessing their attitudes about the hypothetical sensor. The first page of the questionnaire showed a photograph of the proposed sensor (Figure 1A), a diagram of the sensor's placement on the neck (Figure 1B), a brief description of the sensor's purpose, and the proposed timeline of wearing the sensor every weekend from the 3rd month after radiation to the 12th month after radiation, for a total of 9 months.

Main Outcome: Willingness to Wear the Sensor

For studies 1 to 3, the study questionnaire asked whether the patient would have been willing to wear the sensor for 9 months during the first year after radiation, starting from the 3rd month after treatment. This time point was asked about because it would give sufficient time for the skin on their neck to have healed from radiation skin burns. Participants were then asked whether they would have been willing to wear the sensor for the entire 9 months, every other week during the 9-month period, or every weekend during the 9-month period and then a series of branched-logic true-false questions about reasons for their willingness versus unwillingness to wear the sensor. Next, using a 3-point Likert scale response format, all participants rated whether changes in the sensor design (in terms of either unobtrusive appearance or the ability to receive feedback about the risk for dysphagia) would change the individual's willingness or unwillingness to wear the sensor every weekend for 9 months. Additional comments or suggestions were also solicited as free text.

Study 2

Design and Eligibility

A second sample of survivors of head and neck cancer who received radiation treatment 2 to 10 years ago and were attending surveillance visits at MD Anderson's Head and Neck Center gave informed consent and enrolled in study 2, which lasted for 1 week: testing was constrained to a 1-week period in which visiting graduate engineering students from University of California San Diego traveled to MD Anderson for on-patient equipment testing. The eligibility criteria for study 2 were the same as those for study 1; however, we oversampled for patients with a Dynamic Imaging Grade of Swallowing Toxicity score >0, which indicated the presence of radiation-associated dysphagia, as verified using a modified barium swallow test [57]. The oversampling was done to gauge the accuracy of the prototype sensor in distinguishing between survivors with dysphagia and survivors without dysphagia [58]. For every participant with dysphagia, we recruited a patient without dysphagia matched for age and sex. For patients who declined participation, deidentified disease information, demographics, and reason for refusal were noted in the study record.

Procedure and Assessment

A wired prototype graphene strain sensor coupled with a wired surface electromyography sensor was placed on the patient to obtain muscle movement measurements during a series of swallowing tasks involving various bolus textures, as described previously (Figure 1C) [58]. Immediately after the on-throat sensor test, patients were asked to answer 6 questions about the sensor's discomfort, ease of use, and associated embarrassment using a 5-point Likert scale ranging from strongly disagree to strongly agree. Patients were again asked whether they would be willing to wear the sensor for 9 months (but now for once a month on one of the weekends) and then branching questions on reasons for their willingness or unwillingness. Patients were again asked to rate the impact of sensor unobtrusiveness and predictive dysphagic feedback on their willingness to wear the sensor for extended periods. Finally, demographic information regarding age, race, and marital status was extracted from the medical record. All testing sessions were conducted at the Head and Neck Cancer Center at MD Anderson.

Study 3

Design and Eligibility

Similar eligibility, consent, and testing procedures were used in study 3. However, eligible patients were more likely to be approached during active treatment for throat cancer, whereas studies 1 and 2 recruited long-term survivors. Study 3's sensor (Figure 1D) was revised to have better skin conformation and comfort: standard surface electromyography electrodes were replaced with flexible custom dry electrodes, whereas the strain sensor was supported on a silicone substrate [59].

Assessment Procedures

After the completion of the on-throat sensor test, patients were asked the same questions as those asked in study 1 regarding their willingness to wear the sensor for 9 months and whether changes in the sensor's appearance and feedback capability would change their minds about their willingness to wear the sensor. In addition, participants were interviewed regarding the helpfulness of the future capability of the sensor to provide immediate haptic feedback in 3 different scenarios: to indicate the correct placement of the sensor, correct performance of a particular swallowing exercise, and quality of swallowing during at-home testing involving various bolus textures. Their answers were transcribed, categorized, and coded into 3 categories (0=not helpful, 1=helpful under certain conditions, and 2=helpful).

Analysis

Descriptive statistics (eg, proportions, means, ranges, and SDs) were computed for the process evaluation and participant satisfaction data, together with 95% CIs. To assess the external validity of the study, demographic and disease information was compared between respondents and nonrespondents in study 1 (Tables 1-3) and between participants and refusers in studies 2 and 3 (data not shown). All questionnaire responses were analyzed using the SPSS software (IBM Corp).

Table 1. Demographic and disease comparisons between respondents and nonrespondents and between respondents willing to wear the sensor for 9 months and those not willing to wear the sensor for 9 months in study 1.

Characteristics	Potentially eligible survivors from the parent study (n=234)				Survivors who completed the questionnaire (n=138)			
	Total sample	Nonrespondents (did not participate)	Respondents	*P* value	Total sample	Respondents unwilling to wear the sensor for 9 months	Respondents willing to wear the sensor for 9 months	*P* value
What is your age?								
Values, n (%)	234 (100)	96 (41)	138 (59)	N/A[a]	138 (100)	22 (15.9)	116 (84.1)	N/A
Values, mean (SD)	57.4 (10.0)	56.6 (9.8)	58 (10.1)	.28	58 (10.1)	55.2 (9.4)	58.5 (10.1)	.15
What is your ethnic background? n (%)				*.003*[b]				.59
Hispanic or Latino	21 (9.1)	15 (16)	6 (4.4)		6 (4.4)	0	6 (5.2)	
Not Hispanic or Latino	210 (90.9)	79 (84)	131 (95.6)		131 (95.6)	22 (100)	109 (94.8)	
Race, n (%)				.23				.53
African American	10 (4.3)	6 (6.4)	4 (2.9)		4 (2.9)	1 (4.5)	3 (2.6)	
American Indian or Alaska Native	1 (0.4)	1 (1.1)	0 (0)		0	0 (0)	0 (0)	
Asian	6 (2.6)	1 (1.1)	5 (3.64)		5 (3.6)	1 (4.5)	4 (3.5)	

	Native Hawaiian or Pacific Islander	1 (0.4)	0 (0)	1 (0.7)		1 (0.7)	0 (0)	1 (0.9)	
	Non-Hispanic White	213 (92.2)	86 (91.5)	127 (92.7)		127 (92.7)	20 (90.9)	107 (93)	
Education, n (%)					*.02*[c]				.26
	Some college and lower	112 (48.9)	54 (58.1)	58 (42.6)		58 (42.6)	7 (31.8)	51 (44.7)	
	Bachelor's degree or higher	117 (51.1)	39 (41.9)	78 (57.4)		78 (57.4)	15 (68.2)	63 (55.3)	
Employment status, n (%)					.60				.18
	Full time or part time	145 (63.3)	57 (61.3)	88 (64.7)		88 (64.7)	17 (77.3)	71 (62.3)	
	Not employed	84 (36.7)	36 (38.7)	48 (35.3)		48 (35.3)	5 (22.7)	43 (37.7)	
Marital status, n (%)					.50				>.99
	Single and living alone or married but living apart, separated, divorced, or widowed	46 (20)	21 (22.1)	25 (18.5)		25 (18.5)	4 (18.2)	21 (18.6)	
	Single but living with significant other or	184 (80)	74 (77.9)	110 (81.5)		110 (81.5)	18 (81.8)	92 (81.4)	

	married living with spouse								
Occupation, n (%)					.07				.54
	Professional or managerial	143 (71.9)	51 (63)	92 (78)		92 (78)	16 (88.9)	76 (76)	
	Retail, service, or labor	44 (22.1)	24 (29.6)	20 (16.9)		20 (16.9)	2 (11.1)	18 (18)	
	Student or unemployed	12 (6)	6 (7.4)	6 (5.1)		6 (5.1)	0 (0)	6 (6)	
What is your income before taxes? (US $), n (%)					*.007*[b]				.22
	<30,000	38 (18.9)	24 (30.4)	14 (11.5)		14 (11.5)	0 (0)	14 (13.6)	
	30,000-50,000	31 (15.4)	13 (16.5)	18 (14.8)		18 (14.8)	2 (10.5)	16 (15.5)	
	50,000-475,000	28 (13.9)	9 (11.4)	19 (15.6)		19 (15.6)	2 (10.5)	17 (16.5)	
	75,000	104 (51.7)	33 (41.8)	71 (58.2)		71 (58.2)	15 (78.9)	56 (54.4)	
Stage of disease, n (%)					.24				.70
	Stage 1 or 2	76 (32.5)	27 (28.1)	49 (35.5)		49 (35.5)	7 (31.8)	42 (36.2)	
	Stage 3 or 4	158 (67.5)	69 (71.9)	89 (64.5)		89 (64.5)	15 (68.2)	74 (63.8)	

[a]N/A: not applicable.

[b]*P*<.01.

[c]*P*<.05.

Table 2. Demographic and disease comparisons between respondents willing to wear the sensor for 9 months and those not willing to wear the sensor for 9 months in study 2.

Characteristics	Total sample (n=14)	Respondents willing to wear the sensor for 9 months (n=10)	Respondents unwilling to wear the sensor for 9 months (n=4)	*P* value
Age (y), mean (SD)	61.6 (11.5)	61.2 (12.3)	62.8 (11.0)	.83
Race, n (%)				.55
African American	0 (0)	0 (0)	0 (0)	
American Indian or Alaska Native	0 (0)	0 (0)	0 (0)	
Asian	0 (0)	0 (0)	0 (0)	
Native Hawaiian or Pacific Islander	0 (0)	0 (0)	0 (0)	
Non-Hispanic White	13 (93)	9 (90)	4 (100)	
More than 1 race	1 (7)	1 (10)	0 (0)	
What is your ethnic background, n (%)				.85
Hispanic or Latino	3 (21)	2 (20)	1 (25)	
Not Hispanic or Latino	11 (79)	8 (80)	3 (75)	
Occupation, n (%)				.52
Managerial or professional	2 (14)	2 (20)	0 (0)	
Retail, service, or operator	9 (64)	6 (60)	3 (75)	
Student or unemployed	3 (21)	2 (20)	1 (25)	
Marital status, n (%)				.37
Married or living with significant other	12 (86)	8 (80)	4 (100)	
Single, divorced, widowed, or separated	2 (14)	2 (20)	0 (0)	
Dysphagic status, n (%)				.27
Dysphagic (DIGEST[a]>0)	7 (50)	5 (50)	2 (50)	>.99
Not dysphagic (DIGEST=0)	7 (50)	5 (50)	2 (50)	
Disease stage, n (%)				.14
Stage 1 and 2	1 (8)	0 (0)	1 (25)	

	Stage 3 and 4	12 (92)	9 (90)	3 (75)	

[a]DIGEST: Dynamic Imaging Grade of Swallowing Toxicity.

Table 3. Demographic and disease comparisons between respondents willing to wear the sensor for 9 months and those not willing to wear the sensor for 9 months in study 3.

Characteristics	Total sample (n=14)	Willing to wear the sensor for 9 months (n=12)	Unwilling to wear the sensor for 9 months (n=2)	*P* value
Age (y), mean (SD)	62.4 (12.3)	61.0	70.5	.33
Race, n (%)				.57
African American	0 (0)	0 (0)	0 (0)	
American Indian or Alaska Native	0 (0)	0 (0)	0 (0)	
Asian	2 (14)	2 (17)	0 (0)	
Native Hawaiian or Pacific Islander	0 (0)	0 (0)	0 (0)	
Non-Hispanic White	12 (86)	10 (83)	2 (100)	
More than one race	0 (0)	0 (0)	0 (0)	
What is your Ethnic Background? n (%)				.70
Hispanic	1 (7)	1 (8)	0 (0)	
Not Hispanic	13 (93)	11 (92)	2 (100)	
Occupation, n (%)				.87
Managerial or professional	7 (50)	6 (50)	1 (50)	
Retail, service, or operator	6 (43)	5 (42)	1 (50)	
Student or unemployed	1 (7)	1 (8)	0 (0)	
Marital, n (%)				*.01*[a]
Married or living with significant other	10 (	12 (100)	0 (0)	
Single, divorced, widowed, or separated	2 (14)	1 (50)	1 (50)	
Dysphagic status, n (%)				>.99
Dysphagic (DIGEST[b]>0)	7 (50)	6 (50)	1 (50)	
Not dysphagic (DIGEST=0)	7 (50)	6 (50)	1 (50)	
Disease stage, n (%)				.70
Stage 1 and 2	1 (7)	1 (8)	0 (0)	
Stage 3 and 4	13 (93)	11 (92)	2 (100)	

[a]*P*<.05.

[b]DIGEST: Dynamic Imaging Grade of Swallowing Toxicity.

Ethical Considerations

All study materials and procedures were approved by the institutional review board at MD Anderson Cancer Center's Institutional Review Board (protocol 2016-0597). All enrolled participants signed informed consent forms before testing began. All study data were deidentified, and no compensation was provided for participation.

Results

Overview

Before user testing by patients, our study incorporated design input from individuals from multiple disciplines, including behavioral scientists, speech pathologists, radiation oncologists, and engineers. Initially, our primary concern was to develop a wearable device that would not injure the skin sensitized by radiation and would have an uncomplicated application and removal procedure. Various invasive sensors, such as those worn inside the mouth, were dropped from consideration after it was realized that patients would possibly need to use the device during radiation and later at home during the first year after treatment. During study 1, we gathered patient reactions to a photograph of a sensor (Figure 1), whereas in studies 2 and 3, prototype versions were tested on survivors and patients in the clinic (Figure 1). The racial breakdown of the overall study sample was as follows: non-Hispanic White (213/234, 92.2%), African American (10/234, 4.3%), Asian American (6/234, 2.6%), American Indian or Alaska Native (1/234, 0.4%), and Native Hawaiian or Pacific Islander (1/234, 0.4%).

Study 1

The research staff contacted 234 eligible participants to complete study 1's questionnaire, either via REDCap or via mail; of the 234 participants, 138 (59%) completed the questionnaire (Figure 2). Participants in study 1 were primarily non-Hispanic White patients, were married, and had a mean age of 57.4 (SD 10) years (Tables 1-3). The median time since the end of radiation treatment was 4 years and 26 days (Tables 1-3). Analyses of respondents versus nonrespondents showed that respondents were more likely to be non-Hispanic patients, have a bachelor's degree, and have higher annual income; differences in race, age, and disease stage were not significantly different (see Tables 1-3 for specific *p* values).

Survivor Preferences for Wearable Throat Sensor

Of the 138 respondents, 115 (83.3%) agreed that they would have been willing to wear the sensor for 9 months during the first year after radiation. However, patients were not willing to wear the sensor during the work week owing to the fear of coworkers or strangers asking about the sensor. Instead, they were willing to wear the sensor on weekends, but only for one weekend a month, as opposed to every weekend. When presented with several potential reasons explaining their willingness to wear the sensor, nearly all respondents cited altruism, whereas 87.6% (92/105) of the respondents cited interest in the sensor technology, and 77% (75/97) of the

respondents thought that the sensor would help them adhere to their preventive swallowing exercises (Tables 4-6). For example, several patients commented that personalized feedback from the sensor would provide additional motivation to adhere to their preventive swallowing exercises:

It would push me to do my exercises diligently...

It would get me on the ball and do my exercises more often...

It would give me the information I can use to fight back the scar tissue problem. And see the importance of my neck exercises.

Others valued the additional information that the sensor would provide:

I would be curious to know what is going on with my body...

I would have liked to have known what was happening to my throat...

It's my neck! Why wouldn't I want to know?

Table 4. Study 1: number of patients endorsing reasons for their willingness or unwillingness to wear the sensor every weekend for 9 months[a].

Which of the following reasons would motivate you to wear the sensor every weekend for 9 months after radiation?	Patients who would wear the sensor, n (%)		Patients would not wear the sensor, n (%)	
	Patients who selected true	Patients who selected false	Patients who selected true	Patients who selected false
The technology of the patch sounds interesting.	92 (87.6)	13 (12.4)	N/A[b]	N/A
Wearing the patch would have reminded me to do my swallowing exercises.	75 (77.3)	22 (22.7)	N/A	N/A
I wanted to help with MD Andersons research.	108 (99.1)	1 (0.9)	N/A	N/A
My skin was still sensitive during that time.	N/A	N/A	11 (50)	11 (50)
I wouldn't want to put on and take off the patch every weekend.	N/A	N/A	14 (63.6)	8 (36.4)

I wouldn't want to wear the patch for 9 months.	N/A	N/A	19 (86.4)	3 (13.6)
I would feel uncomfortable if people noticed the patch and ask me questions or wanted to talk about it.	N/A	N/A	12 (57.1)	9 (42.9)
I was being asked to participate in too many studies.	N/A	N/A	1 (5.3)	18 (94.7)
It would have added to my daily responsibilities.	N/A	N/A	11 (55)	9 (45)
It would have been a reminder of my cancer treatment.	N/A	N/A	6 (30)	14 (70)
I would not be able to see my data from the patch.	N/A	N/A	6 (28.6)	14 (71.4)

[a]Patients who would wear the sensor: 115/138, 83.3%; patients would not wear the sensor: 23/138, 16.7%.

[b]N/A: not applicable.

Table 5. Study 2: number of patients endorsing reasons for their willingness or unwillingness to wear the sensor every weekend for 9 months[a].

Which of the following reasons would motivate you to wear the sensor every weekend for 9 months after radiation?	Patients who would wear the sensor, n (%)		Patients who would not wear the sensor, n (%)	
	Patients who selected true	Patients who selected false	Patients who selected true	Patients who selected false
The technology of the patch sounds interesting.	8 (80)	2 (20)	N/A[b]	N/A
Wearing the patch would have reminded me to do my swallowing exercises.	10 (100)	0 (0)	N/A	N/A
I wanted to help with MD Andersons research.	10 (100)	0 (0)	N/A	N/A
My skin was still sensitive during that time.	N/A	N/A	1 (25)	3 (75)

I wouldn't want to put on and take off the patch every weekend.	N/A	N/A	2 (50)	2 (50)
I wouldn't want to wear the patch for 9 months.	N/A	N/A	4 (100)	0 (0)
I would feel uncomfortable if people noticed the patch and ask me questions or wanted to talk about it.	N/A	N/A	2 (50)	2 (50)
I was being asked to participate in too many studies.	N/A	N/A	0 (0)	4 (100)
It would have added to my daily responsibilities.	N/A	N/A	3 (75)	1 (25)
It would have been a reminder of my cancer treatment.	N/A	N/A	1 (25)	3 (75)
I would not be able to see my data from the patch.	N/A	N/A	0 (0)	4 (100)

[a]Patients who would wear the sensor: 10/14, 71%; patients who would not wear the sensor: 4/14, 29%.

[b]N/A: not applicable.

Table 6. Study 3: number of patients endorsing reasons for their willingness or unwillingness to wear the sensor every weekend for 9 months[a].

Which of the following reasons would motivate you to wear the sensor every weekend for 9 months after radiation?	Patients who would wear the sensor, n (%)		Patients who would not wear the sensor, n (%)	
	Patients who selected true	Patients who selected false	Patients who selected true	Patients who selected false
The technology of the patch sounds interesting.	12 (100)	0 (0)	N/A[b]	N/A
Wearing the patch would have reminded me to do my swallowing exercises.	12 (100)	0 (0)	N/A	N/A
I wanted to help with MD Andersons research.	12 (100)	0 (0)	N/A	N/A
My skin was still sensitive during that time.	N/A	N/A	0 (0)	2 (100)

I wouldn't want to put on and take off the patch every weekend.	N/A	N/A	0 (0)	2 (100)
I wouldn't want to wear the patch for 9 months.	N/A	N/A	1 (50)	1 (50)
I would feel uncomfortable if people noticed the patch and ask me questions or wanted to talk about it.	N/A	N/A	1 (50)	1 (50)
I was being asked to participate in too many studies.	N/A	N/A	0 (0)	2 (100)
It would have added to my daily responsibilities.	N/A	N/A	2 (100)	0 (0)
It would have been a reminder of my cancer treatment.	N/A	N/A	0 (0)	2 (100)
I would not be able to see my data from the patch.	N/A	N/A	0 (0)	2 (100)

[a]Patients who would wear the sensor: 12/14, 86%; patients who would not wear the sensor: 2/14, 14%.

[b]N/A: not applicable.

Among the 22 unwilling participants who provided data, nearly 90% (24/28, 86%) cited the lengthy duration of having to wear the sensor as one of the reasons for their unwillingness, and 57% (16/28) disliked the idea of having to wear the sensor every weekend. The photograph of the proposed sensor had large black letters embedded within the sensor (Figure 1) to contain its wiring; over half (15/27, 56%) of the unwilling participants objected to the sensor being noticeable enough that others would want to ask questions about its purpose. Less than one-third (7/26, 27%) of the unwilling participants disliked the idea of being reminded of their cancer treatment during the first year after radiation (Tables 4-6). Participants who were unwilling to wear the sensor for 9 months did not have any significant demographic or clinical differences from participants who expressed willingness to wear the sensor.

When asked whether changing the sensor's appearance to that of a Band-Aid would impact their willingness, 29% (4/14) of all study 1 participants agreed that this would increase their willingness, whereas 71% (10/14) stated that an unobtrusive appearance would not affect their willingness (mean 2.45, SD 0.87; Figure 3):

Cosmetics is the least of my worries when I am going through treatment and fighting for my life.

After completing the sensor study, most participants (21/28, 75%) agreed that the sensor's proposed function of delivering individual risk for dysphagia would have increased their willingness (mean 1.5, SD 0.88; Figure 3). Notably, half of the free-text comments indicated that had the participants been able to measure muscle fibrosis earlier, they would have been more diligent about performing their prescribed swallowing exercises. Some simply wrote that they wanted the sensor to be available so that future patients would understand that the risk of dysphagia was high:

I would like to see this in ACTION NOW.

Study 2

Within a 1-week period, a convenience sample of 20 potentially eligible survivors of oropharyngeal cancer who were nonmetastatic and able to speak English was approached at their surveillance visit for enrollment in the study. To test the sensor's performance in distinguishing between normal and dysphagic swallowing patterns, survivors who had developed severe dysphagia owing to their radiation were oversampled for study 2. Potentially eligible survivors were first identified in the electronic medical record; approached during a surveillance visit; and, if consented, scheduled for the sensor-testing session with the engineers in a clinic exam room. Of the 20 patients, 3 (15%) refused to participate, citing fatigue or disinterest: all 3 (100%) were White patients, 2 (67%) were male patients, 1 (33%) was a female patient, and their ages ranged from 63 to 74 years. Of these 3 patients, 2 (67%) were dysphagic, and the 1 (33%) other patient was nondysphagic. All 3 (100%) patients were diagnosed with late-stage oropharyngeal cancer (data not shown). Of the 20 patients approached for participation in study 2, 17 (85%) agreed, but 1 (5%) patient subsequently dropped out because of receiving news of cancer recurrence (Figure 4). Another 2 (10%) participants experienced scheduling conflicts; therefore, informed consent was obtained from the remaining 14 (70%) participants. Consistent with this cancer type's demographic profile, the average age of the sample was 61.6 (SD 11.5) years, with 12 (86%) male participants and 2 (14%) female participants. Of the 14 participants, 3 (21%) were Hispanic or Latino participants, and 3 (21%) were of a racial and ethnic minorities (Tables 1-3). Specific cancer diagnoses included cancers of the oropharynx (9/14, 64%), larynx (3/14, 21%), and nasopharynx (1/14, 7%) and unknown primary cancers (1/14, 7%). The average time since the completion of radiation treatment was 47.9 months, and half (7/14, 50%) of the sample had received a diagnosis of radiation-associated dysphagia (Tables 1-3).

After wearing the sensor, 10 (71%) of the 14 patients indicated that they would have been willing to wear the sensor for 9 months of the first year after radiation treatment. The most prevalent reasons for willingness were wanting to help future patients detect developing dysphagia and wanting to help MD Anderson research (Tables 4-6). Of the 4 (29%) patients who did not think they would have been willing to wear the sensor, the most popular reason for unwillingness was that the study burden was high, specifically, that 9 months was too long of a testing period and that there was an increase in their responsibilities associated with the sensor. On a 5-point Likert response scale, patients' ratings for the discomfort of the sensor (mean 1.21, SD 0.4/2), embarrassment associated with sensor use (mean 1.14, SD 0.36), and difficulty in the application and removal of the sensor (mean 1.5, SD=0.52) were minimal (Tables 7 and 8). Therefore, these questions were not repeated in the next phase of user testing.

Table 7. Study 2's patient ratings for the discomfort of the sensor, embarrassment associated with sensor use, difficulty in the application and removal of the sensor (n=14)[a].

	Patient ratings, mean (SD; range)

The sensor was uncomfortable to wear.	1.21 (0.426; 1-5)
The sensor would be difficult for me to use at home.	1.5 (0.519; 1-5)
I thought the experiment was fun.	3.79 (0.893; 1-5)
The testing session was embarrassing.	1.14 (0.363; 1-5)
I am good about doing my swallowing exercises every day.	3.27 (1.51; 1-5)
I believe it is important for me to do as many of my swallowing exercises as possible.	4.46 (1.13; 1-5)

[a]1=strong agree; 5=strongly disagree.

Table 8. Study 3's patient ratings for the helpfulness of haptic signaling (n=14)[a].

	Patient ratings, mean (SD; range)
Would it help for the sensor itself to vibrate when you put it in the right spot on your throat?	1.85 (0.376; 0-2)
Do you think it would be helpful to have the sensor vibrate once you did your swallowing exercise correctly?	2.00 (0.000; 0-2)
Do you think that having the sensor process your swallowing data and give you feedback about the quality of your swallowing would help?	1.46 (0.555; 0-2)

[a]0=no; 2=maybe.

Study 3

As with study 2, a convenience sample of 14 participants were recruited within a 1-week period to assess user preferences for the updated sensor prototype. Survivors of oropharyngeal cancer who had completed radiation treatment were identified in the medical record and approached during surveillance visits. In addition, patients with oropharyngeal cancer who were undergoing radiation treatment were also approached; therefore, long-term dysphagic status was not yet known for these participants. A total of 17 participants were eligible and approached to participate in the sensor study. Of these 17 patients, 2 (12%) refused, both of whom were White male patients: one patient was aged 76 years and had been diagnosed with late-stage oropharyngeal cancer 2 years before, and the other patient was aged 23 years and was in the third week of radiation treatment for late-stage oropharyngeal cancer (data not shown). The remaining 15 (15 agreed and 17 approached=88%) agreed to participate and provided their informed consent. Of these 15 patients, 1 (7%) developed an acute illness episode the following day and was, therefore, unable to complete the sensor test, resulting in 14 (93%) patients completing user testing (Figure 5). Study 3's sample comprised primarily male (12/14, 86%) and non-Hispanic White (12/14, 86%) patients with an average age of 62 years (Tables 1-3). As in the previous 2 studies, most patients (11/14, 79%) were diagnosed with oropharyngeal cancer. Unlike the previous 2 studies, 11 (79%) of the

14 patients were on active treatment at the time of testing, and the remaining 2 participants were 1- to 5-year survivors (data not shown).

As with the previous studies, most patients (12/14, 86%) indicated willingness to wear the sensor for 9 months during the first year after radiation treatment. Wanting to help future patients detect developing dysphagia and wanting to help MD Anderson research were the most prevalent reasons for willingness (Tables 4-6). As in study 2, the most frequently cited reasons for unwillingness were those related to study burden (lengthy testing period and increase in daily responsibilities; Tables 4-6), and opinions regarding the helpfulness of haptic feedback were obtained from 13 (93%) of the 14 participants. All 13 participants thought that it would be helpful for the sensor to vibrate when placed in the correct spot on the neck (mean 1.85, SD 0.38) and when swallowing exercises were performed correctly (mean 2.0, SD 0.00; Tables 7 and 8). Of the 13 patients, 11 (85%) felt that it would be helpful for the sensor to provide haptic feedback on swallowing quality during at-home testing (mean 1.5, SD 0.88; Tables 7 and 8).

Discussion

Principal Findings

Overview

To our knowledge, this is the first study to assess the evaluation of a wearable throat sensor by patients with head and neck cancer in clinical settings, with separate cohorts at varying time points along their treatment trajectory. Across all studies, the overall willingness to wear the sensor for 9 months during the first year after radiation treatment was high, and the perceived need was rated highly. However, study 1's results should be interpreted with caution, as the participation rate was 59%, with non-Hispanic patients and patients with higher income or education more likely to complete the questionnaire. Although studies 2 and 3 used convenience samples for user testing, accrual rates were high (88%), even for those undergoing active treatment at the time of approach.

Direct comparison of our results with those of other studies is not possible because the vast majority of published studies regarding wearable devices equipped with mechanical, optical, biochemical, electrical, and acoustic sensors are pilot studies conducted with graduate students in a laboratory under highly controlled conditions [60-64]. Although our study did not test actual user engagement over repeated time points, it did gather patients' opinions about the likelihood that they would wear the sensor for a period of several months. This question was asked in study 1 to patients who were only exposed to a photograph of the proposed sensor, whereas patients and survivors in study 2 were asked this question after wearing the actual sensor while swallowing boluses of varying textures in a controlled setting. When searching for comparable studies that addressed extended user engagement with health technologies, the extant literature is limited to nonsensor research with mobile websites or apps [65] and to real-world studies of fitness tracker abandonment rates in healthy adults. These studies tend to describe a steep decline in user engagement over time. It is possible that

our high rates of expressed willingness to wear the sensor for 9 months is due to the perceived usefulness of the device for this highly specialized problem.

As most participants (137/166, 82.5%) expressed willingness to wear the sensor for 9 months, data from the participants who were unwilling provided valuable insight into the potential barriers to the long-term use of the sensor. Across all 3 studies, nearly 86% (24/28) of the unwilling participants who answered the question about chronic use cited the 9-month testing period as being too long. The second most prevalent reason for unwillingness, that the sensor's appearance would provoke unwanted attention, was endorsed by 56% (15/27) of the unwilling participants. The third most frequent reason (16/26, 62%) was an unwanted increase in daily responsibilities. This was also borne out by spontaneous comments in study 3, where nearly all 14 patients communicated a preference for a more streamlined 1-step application process, rather than the separate applications for the strain sensor and surface electromyography electrodes. By contrast, several of the unwilling participants were much more willing to wear the sensor for 9 months if the sensor could provide individual dysphagic risk feedback and was made more unobtrusive in appearance (Figure 3). These findings are consistent with other mHealth reports citing multiple aspects of participant burden [48] and the social implications of the technology's appearance [66] as being relevant constructs to user engagement.

Bidirectional Communication

Two other persuasive design principles were confirmed by our data: the desire for bidirectional communication (dialog support) with the clinical team (system credibility). In all 3 studies, a large proportion of patients endorsed the rationale for the sensor (115/138, 83.5%; 10/14, 71%; and 12/14, 86%, respectively), that is, sensor data are processed and sent back with contextual explanations of their risk of dysphagia development. Furthermore, of the 3 proposed persuasive design features, feedback on dysphagia risk had the greatest impact on increasing willingness among all participants (Tables 7 and 8). These findings point to the importance of fostering a sense of connectedness and reassurance between the user and technology so that the patient's association between their own health behaviors and subsequent health outcomes can be continually reinforced [42]. Future plans for implementation include the visualization of the near-time individualized risk for dysphagia by using an app that can be linked to the throat sensor. When asked about direct haptic communication with the sensor itself, patients in study 3 rated haptics as helpful, especially when unsure about the correct placement of the sensor on the throat and whether preventive exercises were being performed correctly (Tables 7 and 8). One of the patients commented that he was never really sure whether he was performing the exercises correctly at home and was "just winging it."

Sensor and Adherence to Exercises

Most participants (97/119, 81.5%) agreed that the sensor would serve as a reminder for them to do their speech pathology swallowing exercises. Although the main goal of the sensor is to provide earlier detection of radiation-associated dysphagia, reminding patients to complete their swallowing exercises at home to counteract

the development of dysphagia could be an additional benefit to this developing technology. Because personalized risk information is generally not sufficient in itself to increase exercise adherence per se [67], further user-centered testing would be needed to assess preferred modes of sensor feedback (eg, within an app or coupled with web-based coaching) [68].

Limitations

Our study was conducted solely with survivors and patients of head and neck cancer who were attending clinical visits at MD Anderson, which generally requires high-quality insurance for access. The generalizability of our results is further limited because of the demographic patterns among respondents versus nonrespondents in study 1. Overall, 38% (21/55) of the eligible survivors did not complete the questionnaire despite repeated contact by the study team; nonrespondents were significantly more likely to be Hispanic patients (P=.003), be without a bachelor's degree (P=.02), and have a lower annual household income than respondents (P=.007). This is consistent with the recent analysis of National Cancer Institute's 2018 Health Information National Trends population survey data by Rising et al [69], which showed that nonusers of personal mHealth technologies were more likely to be aged >65 years and have lower incomes. Given the challenge of sustaining patient engagement with mHealth technology, future research should target patients who fit the above-mentioned demographic profiles. Finally, the sample sizes for study 2's and 3's on-patient testing were constrained by the need to complete all testing within a 1-week period, as the sensors were applied or tested by visiting engineers and not by the M D Anderson research staff. It is quite conceivable that larger sample sizes might have produced a wider variation in response to the sensor's features and perceived usefulness.

Conclusions

Large proportions of non-Hispanic, well-educated patients with high-quality insurance and above-average incomes were receptive to the idea of wearing a personalized risk sensor for an extended period during the first year after radiation treatment. User ratings of discomfort and difficulty were minimal; however, a significant minority of patients expressed concern about various aspects of the sensor's burden and appearance.

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Conflicts of Interest

None declared.

Abbreviations

mHealth: mobile health

REDCap: Research Electronic Data Capture

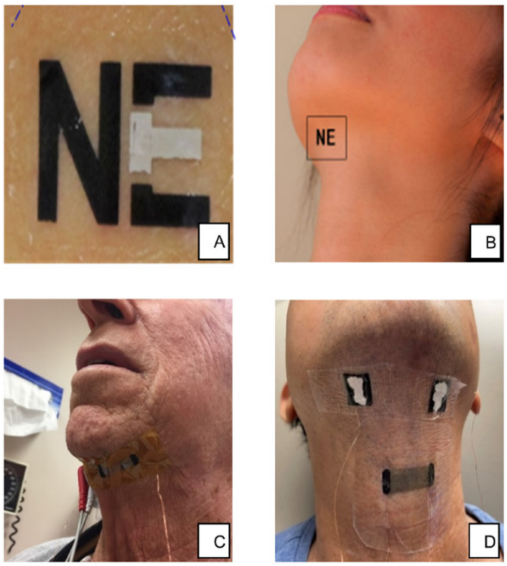

Figure 1. Appearance of hypothetical and actual sensor prototypes. (A) Study 1 respondents were shown a photograph of the proposed sensor and (B) its proposed location on the neck. (C) Study 2's graphene strain sensor prototype, supported on 13-µm-thick polyimide tape (contact surface is silicone) and placed on the submental region probing muscle contraction. (D) Study 3's soft polymer strain sensor, now placed under the laryngeal prominence to capture movement during swallowing.

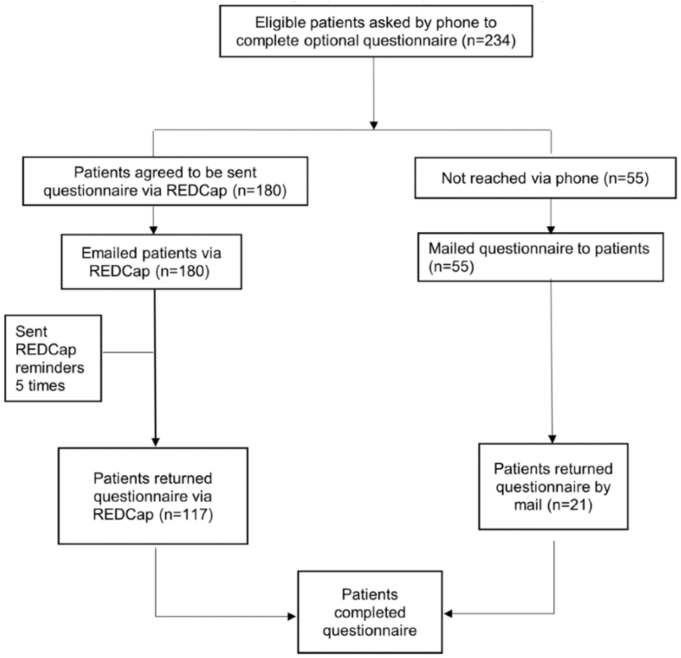

Figure 2. Recruitment CONSORT (Consolidated Standards of Reporting Trials) for study 1 (n=138). REDCap: Research Electronic Data Capture.

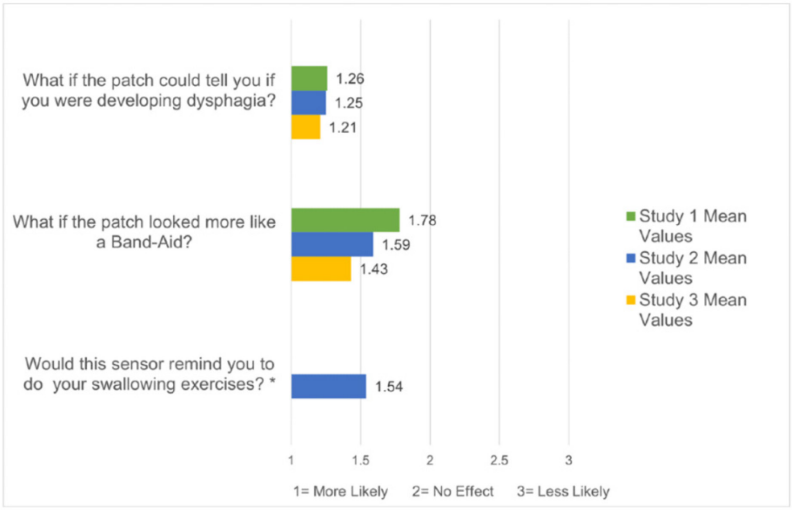

Figure 3. Studies 1 to 3: design feature impact on willingness to use the sensor for 9 months. *Only the participants in study 2 (n=14) were asked this question.

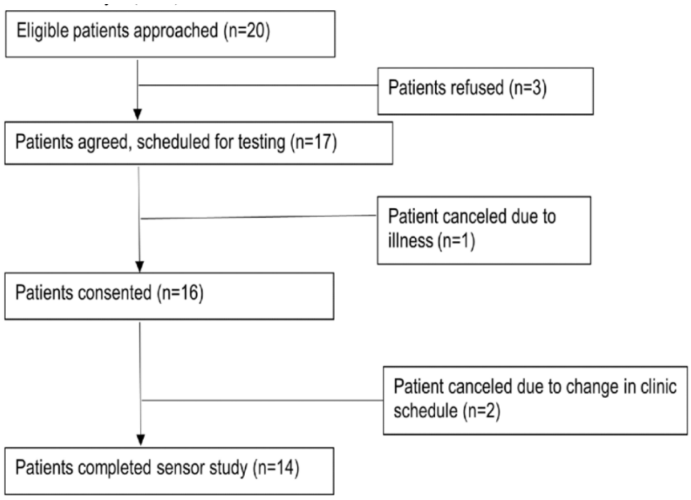

Figure 4. Recruitment flowchart for study 2 (n=14).

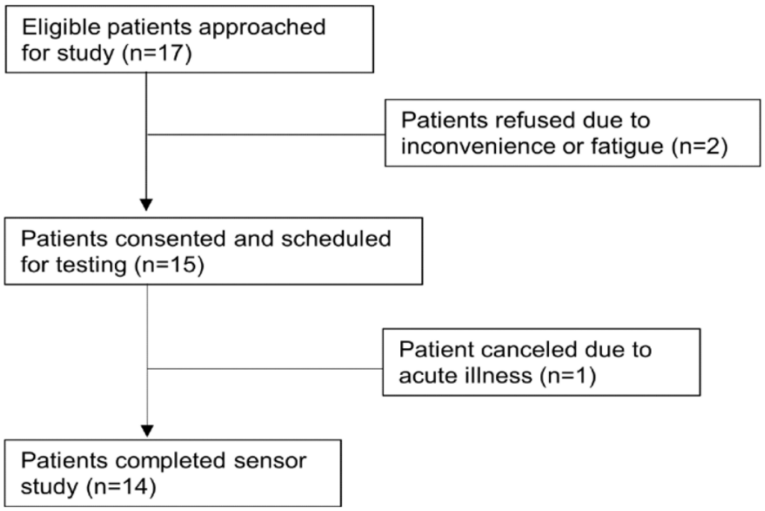

Figure 5. Recruitment flowchart for study 3 (n=14).