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

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Abstract

Background: Frequent, sensor-assisted monitoring of changes in swallowing function may help improve detection of radiation-associated dysphagia before it becomes permanent. While our group has prototyped an epidermal strain/sEMG sensor that can detect minute changes in swallowing muscle movement, it is unknown whether head and neck cancer patients would be willing to wear such a device at home after radiation for several months. We iteratively assessed patients' design preferences and perceived barriers to long-term use of the prototype sensor.

Objective: N/A

Methods: Study 1: Questionnaire only. Pharyngeal cancer survivors who were 3-5 years post-treatment and part of a larger prospective study were asked their design preferences for a hypothetical throat sensor and rate their willingness to use the sensor at home during the first year after radiation. Studies 2-3: Iterative user-testing. Head and neck cancer patients/survivors attending visits at MD Anderson's Head and Neck Center were recruited for two rounds of on-throat testing with prototype sensors while completing a series of swallowing tasks. Afterward, participants were asked about willingness to use the sensor during the first-year post-radiation; 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: Willingness to wear the sensor for 9 months: The majority of respondents in Study 1 (83%; n=138) were willing to wear the sensor 9 months after radiation and participant willingness rates were similar in studies 2 (71.4%; n=14) and Study 3 (85.7%; n=14). Reasons for unwillingness: The most prevalent reasons for participant unwillingness were 9 months being excessive, unwanted increase in responsibility, and feeling self-conscious. Most persuasive design features: Across all three studies, the sensor's ability to detect developing dysphagia increased willingness the most compared to its appearance and ability to increase adherence to preventive speech pathology exercises. Direct haptic signaling was also rated highly, especially to indicate 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. A

significant minority of patients expressed concern with various aspects of the sensor’s burden and its appearance. Clinical Trial: ClinicalTrials.gov NCT03010150

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ABSTRACT

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

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

Method: *Study 1: Questionnaire only*. Pharyngeal cancer survivors who were 3-5 years post-treatment and part of a larger prospective study were asked their design preferences for a hypothetical throat sensor and rate their willingness to use the sensor at home during the first year after radiation. *Studies 2-3: Iterative user-testing*. Head and neck cancer patients/survivors attending visits at MD Anderson's Head and Neck Center were recruited for two rounds of on-throat testing with prototype sensors while completing a series of swallowing tasks. Afterward, participants were asked about willingness to use the sensor during the first-year post-radiation; In study 2, patients also rated the sensor's ease of use, and comfort whereas in study 3, preferences were elicited regarding haptic feedback.

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n=138) were willing to wear the sensor 9 months after radiation and participant willingness rates were similar in studies 2 (71.4%; n=14) and Study 3 (85.7%; n=14). *Reasons for unwillingness*: The most prevalent reasons for participant unwillingness were 9 months being excessive, unwanted increase in responsibility, and feeling self-conscious. *Most persuasive design features*: Across all three studies, the sensor's ability to detect developing dysphagia increased willingness the most compared to its appearance and ability to increase adherence to preventive speech pathology exercises. Direct haptic signaling was also rated highly, especially to indicate correct sensor placement and swallowing exercise performance.

Conclusion: 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. A significant minority of patients expressed concern with various aspects of the sensor's burden and its appearance.

Trial Registration: ClinicalTrials.gov NCT03010150

Keywords: User-centered design, head and neck cancer patients, dysphagia throat sensor

Introduction

In 2021, approximately 32,000 Americans developed laryngeal or pharyngeal cancer, which has a 5-year survival rate of 61% for all stages combined.[1] Management of these cancers often include high-dose intensity-modulated radiation therapy (IMRT) designed to spare pharyngeal muscles and reduce the incidence of radiation-associated dysphagia (swallowing difficulty).[2] Still, a range of studies have reported that roughly 60% of IMRT patients developed long-term swallowing problems within 2 years after radiation had 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 early detection of radiation-associated fibrosis do not yet exist in the U.S. Instead, gold-standard modified barium swallow (MBS) and fiberoptic endoscopic evaluation of swallowing (FEES) tests are typically ordered after the patient begins to complain of difficulties with swallowing. [12] Furthermore, preventive swallowing therapies are not always prescribed prior to the development of radiation-associated dysphagia.[28-30] Unfortunately, once radiation associated dysphagia is clinically detected, there is little hope of 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 is currently possible in the clinical setting. Providing patients with personalized feedback regarding dysphagia risk or subclinical change 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 initiation of intensive speech language therapies.[33] To this end, researchers have developed myriad devices that can be worn on the skin and measure a range of mechanical, optical, biochemical, electrical and/or 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 head and neck cancer survivors, repeated at-home monitoring over a period of months if not years is necessary to demonstrate a clinical advantage over current treatment paradigms. Unfortunately, most mobile technologies fail to engage patients over sustained durations, with most mHealth interventions for chronic disease reporting steep declines in usage, 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 implementation of user experience, and frustration with technical issues.[44-47]

To counter these barriers, it is widely agreed that user-centered testing be employed in a sustained and iterative fashion during the design and development of new health technology. 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 to maximize their potential to effect changes in patients' attitudes and health behaviors. Oinas-Kukkonen & Harjumaa's Persuasive System Design model describes four 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, e.g. via online community forums), dialogue support (providing feedback to the user in a manner that helps user move toward their goal, e.g., with praise and rewards), and system credibility (the

perceived clinical expertise embedded within the sensor output).[49] Relatively few mHealth interventions conduct user-centered testing during technology development, which may be one reason for diminishing patient engagement and eventual abandonment.[50-53] In the US market, the user abandonment rate of fitness trackers is 50% within 6-12 months.[44, 54] Patient abandonment rates are higher for those aged 70 and above: one study found that 43% of their sample had abandoned their sleep and activity trackers within the first two weeks of use.[55]

A recent review of 51 mHealth intervention studies targeting chronic diabetes, cardiovascular or pulmonary diseases noted that diminished patient engagement was prevalent and posed a significant threat to effective use of the technology. Accordingly, nonsignificant effects on clinical markers outweighed significant findings two to one.[42] Therefore, our study explicitly addressed the design of a wearable sensor with the future intended use of 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 since repeated measurements over time would be needed to detect patterns of developing dysphagia in post-treatment patients.

Goal of this study

We conducted assessment with head and neck cancer patients and survivors to determine their needs and preferred characteristics regarding the design of a wearable sensor to deliver personalized risk of dysphagia. Specifically, we assessed perceived barriers to wearing the sensor for 9 months and the impact of proposed design features on willingness to wear the sensor for 9 months, starting at month three after the end of radiation treatment (to allow for healing from radiation skin burn) until the twelfth month post-treatment. In the first of three iterative user-centered tests, we surveyed a large cohort of head and neck cancer survivors who were 4-5 years past radiation treatment 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 head and neck cancer patients undergoing active treatment, to get 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 (EMG) 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, as well as new questions about bidirectional feedback in the form of haptic (vibration) signaling.

Methods

Study 1

Design and eligibility

Head and neck survivors who were still alive and 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: a) had received radiation with curative intent for oropharyngeal (stage II-IVb), laryngeal (II-IVb), hypopharyngeal (I-IVb), nasopharyngeal cancer (I-IVb), or for an unknown primary cancer with cervical metastases, b) were at least two years post treatment, c) were at least 18 years of age, and d) spoke English. Men and women were excluded if they had a) had treatment for previous head and neck cancer, b) a history of previous head and neck surgery (previous biopsy, tonsillectomy and/or tracheotomy were allowed), c) had other cancer diagnoses, except non-melanoma skin cancer or d) history of current oropharyngeal dysphagia unrelated to cancer diagnosis (e.g., dysphagia due to 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 77.0%; demographic and disease information was collected at baseline. Those patients who were already enrolled in the psychosocial parent study and still alive (n=234) were contacted by phone to determine if 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 onto study 1. After obtaining informed consent, participants completed the optional questionnaire administered either by REDCap, telephone or mail at a single timepoint.[56] For mailed questionnaires, a research staff person's phone number was provided if the patient had any questions about the questionnaire.

Measures

Demographic information regarding age, race/ethnicity, employment, income and marital status were obtained by questionnaire. Disease stage was abstracted from the medical record. Participants then completed a questionnaire. The first page of the questionnaire showed a photograph of the proposed sensor (Figure 1A) and a diagram of the sensor's placement on the neck (Fig 1B), a brief description of the sensor's purpose, and the proposed timeline of wearing the sensor every weekend from the 3rd month post-radiation to the 12th month post-radiation, for a total of 9 months.

Main Outcome: Willingness to wear the sensor. For Studies 1-3, 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 in month three post-treatment. This timepoint was asked about since it would give sufficient time for the skin on their neck to have healed from radiation skin burn. Participants were then asked whether they would have been willing to wear the sensor for the entire 9 months, every other week, or every weekend during the 9-month period, and then a series of branched- logic true-false questions about reasons for willingness vs unwillingness to wear the sensor. Next, using a 3-point Likert scale response format, all participants rated whether changes in the sensor design

(either unobtrusive appearance or the ability to receive feedback about 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 head and neck survivors who were two to 10 years post-radiation and attending surveillance visits at MD Anderson gave informed consent and enrolled onto the study during a one-week period: testing was constrained to a one-week period in which visiting graduate engineering students from UC San Diego traveled to MD Anderson for on-patient equipment testing. The eligibility criteria for Study 2 were the same as for Study 1; however, we oversampled for patients with DIGEST Score >0, indicating radiation-associated dysphagia that had been verified with MBS.[57] The oversampling was done to gauge the accuracy of the prototype sensor in distinguishing between dysphagic survivors and survivors without dysphagia.[58] For every dysphagic participant, we recruited a nondysphagic patient matched for age and sex. For patients who declined participation, de-identified 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 EMG sensor was placed on the patient to obtain muscle movement measurements during a series of swallowing tasks of various bolus textures, as described previously (Figure 1C).[58] Immediately after the on-throat sensor test, patients were asked to answer six questions about the sensor's discomfort, ease of use, and associated embarrassment using a five-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 the weekends) with branching questions asking for reasons for willingness vs unwillingness. Patients were again asked to rate the impact of sensor unobtrusiveness and predictive dysphagic feedback on willingness to wear the sensor for extended periods. Finally, demographic information regarding age, race and marital status were abstracted 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 Study 1-2 recruited long-term survivors. Study 3's sensor (Figure 1D) was revised to have better skin conformation and comfort: standard sEMG electrodes were now replaced with flexible custom dry electrodes whereas the strain sensor was supported on a silicone substrate.[59]

Assessment procedures

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

Analysis

Descriptive statistics (e.g., proportions, means, ranges, SD) were computed for the process

evaluation and participant satisfaction data, together with 95% confidence intervals. To assess the external validity of the study, demographic and disease information was compared between respondents and non-respondents were Study 1(Table 1) and between participants and refusers in Studies 2-3 (data not shown). All questionnaire responses were analyzed with Statistical Package for Social Sciences (SPSS).

Table 1: Demographic/ disease comparisons between willing and unwilling participants, Studies 1-3

Study 1	**Potentially Eligible Survivors (n=234 from parent study)**				**Survivors who completed the questionnair (n=138)**			
	Study 1 Participants and Nonparticipants							
Characteristic	**Total N (%)**	**Non-respondent (Did not participate) N (%)**	**Respond-ent N (%)**	***P***	**Total N (%)**	**Willing to wear for 9 mos N (%)**	**Unwilling N (%)**	***P***
What is your age?								
N	234	96 (41.0)	138 (58.9)		138	22	116	
Mean (SD)	57.4 (10.0)	56.6 (9.8)	58 (10.1)	0.28	58 (10.1)	55.2 (9.4)	58.5 (10.1)	0.
Median (Min-Max)	58 (18-83)	56 (30-79)	59 (18-83)		59 (18-83)	56.5 (35-75)	59 (18-83)	
What is your ethnic background?				**0.003**				0.
Hispanic or Latino	21 (9.1)	15 (16.0)	6 (4.4)		6 (4.4)	0	6 (5.2)	
Not Hispanic or Latino	210 (90.9)	79 (84.0)	131 (95.6)		131 (95.6)	22 (100.0)	109 (94.8)	
Race				0.23				0.
American Indian or Alaska Native	1 (0.4)	1 (1.1)	0		0	0	0	
Non-Hispanic White	213 (92.2)	86 (91.5)	127 (92.7)		127 (92.7)	20 (90.9)	107 (93.0)	
African American	10 (4.3)	6 (6.4)	4 (2.9)		4 (2.9)	1 (4.5)	3 (2.6)	
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	1 (0.7)		1 (0.7)	0	1 (0.9)	
Education				**0.02**				0.
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				0.60				0.

Full-time/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								
Single living alone/married but living apart/ separated/ divorced/ widow	46 (20.0)	21 (22.1)	25 (18.5)		25 (18.5)	4 (18.2)	21 (18.6)	
Single but living with significant other/married living with spouse	184 (80.0)	74 (77.9)	110 (81.5)		110 (81.5)	18 (81.8)	92 (81.4)	
Characteristic	**Total N (%)**	**Non-respondent N (%)**	**Respond-ent N (%)**	***P***	**Total N (%)**	**Willing to Wear 9 *m* N (%)**	**Unwilling N (%)**	
Occupation				0.07				0.
Professional/ Managerial	143 (71.9)	51 (63.0)	92 (78.0)		92 (78.0)	16 (88.9)	76 (76.0)	
Retail/ Service/ Labor	44 (22.1)	24 (29.6)	20 (16.9)		20 (16.9)	2 (11.1)	18 (18.0)	
Student/ Unemployed	12 (6.0)	6 (7.4)	6 (5.1)		6 (5.1)	0	6 (6.0)	
What is your income before taxes?				**0.007**				0.
<$30,000	38 (18.9)	24 (30.4)	14 (11.5)		14 (11.5)	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				0.24				0.
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)	
	Study 2 (n=14)				**Study 3 (n=14)**			
Characteristic	Total Sample	Willing to wear 9 *m* (n=10)	Unwilling (n=4)	*P*	Total Sample	Willing to wear 9 *m* (n=12)	Unwilling (N=2)	
Age	61.6	61.2	62.3	.83	62.36	61.0	70.5	
Race				.55				.5
Non-Hispanic White	71.4 %	90	100		85.7%	83.3%	16.7%	
Ethnicity				.73				.7
Hispanic	25%	.22	.33		7.1%	100%	0%	
Occupation				.52				.8
Managerial/ Professional	21.4%	20%	0%		50%	50%	50%	

Retail, Service, Operator	57.1%	60%	75%		42.9%	41.7%	50%	
Student or Unemployed	21.4%	20%	25%		7.1%	8.3%	0%	
Marital		80%	100%	.37				**.**
Married/ Living with Significant Other	85.7%	83.3%	100%		85.7%	100%	0%	
Single/ Divorced/ Widowed/ Separated	14.3%	16.7%	0%		14.3%	50%	50%	
Dysphagic Status	14			0.27				
Dysphagic (DIGEST>0)	50%							
Not dysphagic (DIGEST= 0)	50%							
Disease Stage				0.59				0.
I-II	31%				43%			
III-IV	69%				57%			

Ethics Approval

All study materials and procedures were approved by the Institutional Review Board at MD Anderson Cancer Center's IRB4 (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

Prior to patient user-testing, our study incorporated design input from multiple disciplines, including behavioral scientists, speech pathologists, radiation oncologists, and engineers. Initially, our primary concerns were to develop a wearable device which would not injure skin sensitized by radiation and 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 post-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 (Figure1). The racial breakdown of the overall study sample was: non-Hispanic white (92.2%), African American (4.3%), Asian American (2.6%), American Indian/ Alaska native (0.4%),

Native Hawaiian/ Pacific Islander (0.4%).

Study 1

Research staff contacted 234 eligible participants to complete Study 1's questionnaire, either via REDCap or by mail; 138 participants (59%) completed the questionnaire (Figure 2). Participants in study 1 were primarily non-Hispanic white, married, and their median age was 57.8 years (Table 1; 1.7 SD). Median time since end of radiation treatment was 4 years, 26 days (Table 1). Analyses of responders vs non-responders showed that responders were more likely to be non-Hispanic, more likely to have a bachelor's degree, and have higher annual income; differences in race, age and disease stage were not significantly different (Table 1).

Survivor Preferences for Wearable Throat Sensor

Of the 138 respondents, 116 (83.5%) 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 due to fear of co-workers 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 participants cited altruism, whereas 87% cited interest in the sensor technology, and 77% thought that the sensor would help them adhere to their preventive swallowing exercises (Table 2). For example, several patients commented that the 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?"

Among the 22 participants who indicated that they would have been unwilling to wear the sensor, nearly 90% of all unwilling participants cited the lengthy duration of having to wear the sensor, and 64% 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 of the unwilling participants objected to the sensor being noticeable enough that others would want to ask questions about its purpose. Just under one-third of unwilling participants disliked the idea of being reminded of their cancer treatment during the first year after radiation (Table 2). Participants who were unwilling to wear the sensor for 9 months did not have any significant demographic or clinical differences compared to participants who expressed willingness to wear the sensor.

Table 2. Studies 1-3: Number of Patients Endorsing Reasons for Willingness/ Unwillingness to wear the sensor every weekend for 9 months

STUDY 1 (n=138)				
Reasons for Willingness/ Unwillingness to wear the sensor for 9 months	Would wear sensor N= 115 (83.5%)		Would not wear sensor N=23 (16.5%)	
Which of the following reasons would motivate you to wear the sensor every weekend for 9 months after radiation?	True	False	True	False
The technology of the patch sounds interesting.	92 (87.6%)	13 (12.4%)		
Wearing the patch would have reminded me to do my swallowing exercises.	75 (77.3%)	22 (22.7%)		
I wanted to help with MD Andersons research.	108 (99.1%)	1 (0.9%)		
My skin was still sensitive during that time.			11 (50%)	11 (50%)
I wouldn't want to put on and take off the patch every weekend.			14 (63.6%)	8 (36.4%)
I wouldn't want to wear the patch for 9 months.			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.			12 (57.1%)	9 (42.9%)
I was being asked to participate in too many studies.			1 (5.3%)	18 (94.7%)

It would have added to my daily responsibilities.			11 (55.0%)	9 (45.0%)
It would have been a reminder of my cancer treatment.			6 (30.0%)	14 (70%)
I would not be able to see my data from the patch.			6 (28.6%)	14 (71.4%)
STUDY 2 (N=14)				
Reasons for Willingness/ Unwillingness	Would wear sensor N= 10 (71.4%)		Would not wear sensor N=4 (28.5%)	
Which of the following reasons would motivate you to wear the sensor every weekend for 9 months after radiation?	True	False	True	False
The technology of the patch sounds interesting.	8 (80%)	2 (20%)		
Wearing the patch would have reminded me to do my swallowing exercises.	10 (100%)	0 (0%)		
I wanted to help with MD Andersons research.	10 (100%)	0 (0%)		
My skin was still sensitive during that time.			1 (25%)	3 (75%)
I wouldn't want to put on and take off the patch every weekend.			2 (50%)	2 (50%)
I wouldn't want to wear the patch for 9 months.			4 (100%)	0 (0%)
I would feel uncomfortable if people noticed the patch and ask me questions or wanted to talk about it.			2 (50%)	2 (50%)
I was being asked to participate in too many studies.			0 (0%)	4 (100%)
It would have added to my daily responsibilities.			3 (75%)	1 (25%)
It would have been a reminder of my cancer treatment.			1 (25%)	3 (75%)
I would not be able to see my data from the patch.			0 (0%)	4 (100%)
STUDY 3 (n=14)				
Reasons for Willingness/ Unwillingness	Would wear sensor N= 12 (85.7%)		Would not wear sensor N=2 (14.3%)	
Which of the following reasons would motivate you to wear the sensor every weekend for 9 months after radiation?	True	False	True	False
The technology of the patch sounds interesting.	12 (100%)	0 (0%)		
Wearing the patch would have reminded me to do my swallowing exercises.	12 (100%)	0 (0%)		
I wanted to help with MD Andersons research.	12 (100%)	0 (0%)		
My skin was still sensitive during that time.			0 (0%)	2 (100%)

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

When asked whether changing the sensor's appearance to that of a Band-Aid would impact willingness, 26% of all Study 1 participants agreed that this would increase their willingness whereas 71% stated that unobtrusive appearance would not affect their willingness (M= 2.45, SD=.87; Figure 5):

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

When asked about the sensor's proposed function of delivering individual risk for dysphagia, the majority of the sample (75%) agreed that this feature would increase their willingness (M= 1.5, SD=.88; Figure 5). Notably, half of the free-text comments indicated that had they 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 one-week period, convenience sample of twenty potentially eligible oropharyngeal

cancer survivors who were nonmetastatic and able to speak English were approached at their surveillance visit for period enrollment onto the study. To test the sensor's performance in distinguishing between normal and dysphagic swallowing patterns, survivors who had developed severe dysphagia as a result of 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 with the engineers for the sensor testing session in a clinic exam room. Three patients refused to participate, citing fatigue or disinterest: all were white, two were male and one female, and their age ranged from 63 to 74. Two of the patients were dysphagic and the third was non-dysphagic. All three had been diagnosed with late-stage oropharynx cancer (data not shown). Seventeen patients agreed (85%), but one patient subsequently dropped out due to receiving news of cancer recurrence (Figure 3). Another two participants experienced scheduling conflicts; informed consent was obtained from the remaining 14 participants. Consistent with this cancer type's demographic profile, the average age of the sample was 61, with twelve male participants and two female participants. Three participants were Hispanic or Latino and three were of non-White race (Table 1). Specific cancer diagnoses included cancer of the oropharynx (64%), larynx (21%), nasopharynx (7%), and unknown primary (7%). The average time since completion of radiation treatment was 47.9 months, and half of the sample had received a diagnosis of radiation-associated dysphagia (Table 1).

After wearing the sensor, 10 of the 14 patients (71%) indicated that they would have been willing to wear the sensor for 9 months of the first-year post-radiation. The most prevalent reasons for willingness were wanting to help future patients detect developing dysphagia and wanting to help MD Anderson research (Table 2). Of the four patients (29%) who did not think they would have been willing to wear the sensor, the most popular reason for unwillingness was study burden, specifically, that 9 months was too long of a testing period and the increased responsibilities associated with the sensor. Using a 5-point Likert response scale, patient ratings of discomfort (M= 1.21; SD= 0.42),

embarrassment (M= 1.14; SD= 0.36), and difficulty in application and removal (M= 1.5; SD= 0.52), were minimal (Table 3). Therefore, these questions were not repeated in the next phase of user testing.

Table 3. Study 2's mean patient ratings for sensor discomfort, embarrassment, difficulty of application (n=14) and Study 3's mean patient ratings of helpfulness for haptic signaling(n=14).

STUDY 2 (n=14)				
			Range	
	Mean Patient Ratings	Standard Deviation (SD)	1= Strongly Disagree	5= Strongly Agree
The sensor was uncomfortable to wear	1.21	.426	1.0	5.0
The sensor would be difficult for me to use at home	1.5	.519	1.0	5.0
I thought the experiment was fun	3.79	.893	1.0	5.0
The testing session was embarrassing	1.14	.363	1.0	5.0
I am good about doing my swallowing exercises every day	3.27	1.51	1.0	5.0
I believe it is important for me to do as many of my swallowing exercises as possible	4.46	1.13	1.0	5.0
STUDY 3 (n=14)				
			Range	
	Mean Patient Ratings	Standard Deviation (SD)	0= No	2= Maybe
Would it help for the sensor itself to vibrate when you put it in the right spot on your throat?	1.85	.376	0	2.0
Do you think it would be helpful to have the sensor vibrate once you did your swallowing exercise correctly?	2.00	.000	0	2.0
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	.555	0	2.0

Study 3

As with Study 2, a convenience sample of 14 participants were within a one-week period to assess user preferences to the updated sensor prototype. Oropharyngeal cancer survivors

who had completed radiation were identified in the medical record and approached during surveillance visits. In addition, oropharyngeal cancer patients who were undergoing radiation were also approached; therefore, long-term dysphagic status was not yet known for these participants. Seventeen participants were eligible and approached to participate in the sensor study. Two patients refused, both were white males: One patient was aged 76 and had been diagnosed with late-stage oropharyngeal cancer two years prior, the other was aged 23, and was in the 3rd week of radiation for late-stage oropharynx cancer (data not shown). Fifteen participants (83%) agreed to participate and gave informed consent. One participant developed an acute illness episode the following day and was therefore unable to complete the sensor test, leaving 14 participants who completed user testing (Figure 4). Study 3's sample was primarily male (86%) and non-Hispanic white (86%) with an average age of 62 (Table 1). As in the previous two studies, the majority of patients were diagnosed with oropharyngeal cancer (79%). Unlike the previous two studies, 11 of the 14 (78.6%) were on active treatment at the time of testing, the remaining two participants were 1-5 year survivors (data not shown).

As with the previous studies, the majority of patients (86%) indicated willingness to wear the sensor for 9 months during the first-year post-radiation. Wanting to help future patients detect developing dysphagia and wanting to help MD Anderson research were the most prevalent reasons for willingness (Table 2). As in study 2, the most oft-cited reasons for unwillingness were that of study burden (lengthy testing period and increase in daily responsibilities; (Table 2) Patients' opinions regarding the helpfulness of haptic feedback were obtained for 13 of the 14 participants. All 13 participants thought it would be helpful for the sensor to vibrate when placed in the correct spot on the neck (M= 1.85; SD= .38) as well as when swallowing exercises were performed correctly (M= 2.0; SD=0.00; Table 3. Eleven (85%) participants felt it would be helpful for the sensor to give haptic feedback of swallow quality during at-home testing (M= 1.5; SD= .88; Table 3).

Discussion

To our knowledge, this is the first study is the first to assess head and neck cancer patient evaluations of a wearable throat sensor in clinical settings, with separate cohorts at varying timepoints along their treatment trajectory. Across all studies, the overall willingness to wear the sensor for 9 months during the first year after radiation was high and the perceived need was rated highly. However, Study 1's results should be interpreted with caution since the participation rate was 59%, with non-Hispanic and higher-income/education patients more likely to complete the questionnaire. While Study 2-3 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 other works is not possible since the vast majority of published data regarding wearable devices equipped with mechanical, optical, biochemical, electrical and/or acoustic sensors are pilot studies conducted with graduate students in the laboratory under highly controlled conditions. [60-64] While it did not test actual user engagement over repeated timepoints, 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 for patients who were only exposed to a photo 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 address extended user engagement with health technologies, the extant literature is limited to non-sensor 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 nine months is due to the perceived usefulness of this device for this highly specialized problem.

Since the majority of participants (81% of the total sample) expressed willingness to wear the sensor for 9 months, data from those participants who were unwilling provided valuable insight into

the potential barriers of its long-term use. Across all three studies, nearly 80% of the unwilling participants perceived the 9-month testing period as too long. The second most prevalent reason, that the sensor's appearance would provoke unwanted attention, was endorsed by 71% of the unwilling participants. The third most frequent reason was an unwanted increase in daily responsibilities (62%). This was also born out by spontaneous comments in study 3, when nearly all 14 patients communicated a preference for a more streamlined one-step application process, rather than the separate applications for the strain sensor and sEMG electrodes. On the other hand, 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 were made more unobtrusive in appearance (Figure 5). These findings are consistent with other mHealth reports citing multiple aspects of participant burden [48] and 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 their clinical team (system credibility). In all three studies, a large proportion of patients endorsed the rationale for the sensor (83.5%, 71.4%, 85.7%, respectively) i.e., that sensor data be processed and sent back with contextual explanations of their risk of dysphagia development. Furthermore, of the three proposed persuasive design features, feedback about dysphagia risk had the greatest impact in increasing willingness among all participants (Table 3). These findings point to the importance of fostering a sense of connectedness and reassurance between the user and the technology so that patients' association between their own health behaviors and subsequent health outcomes can be continually reinforced. [42] Future plans for implementation include data visualization of near-time individualized risk for dysphagia in the form of an app that can be linked with 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 correct placement on the throat and whether preventive exercises were being

done correctly (Table 3). One patient commented that he was never really sure if was performing the exercises correctly at home and was “just winging it.”

Sensor and adherence to exercises

The majority of participants (77.3%) agreed that the sensor would serve as a reminder for them to do their speech pathology swallowing exercises. While 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. Since 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 (e.g., within an app or coupled with virtual coaching). [68]

Limitations

Our study was conducted solely with survivors and patients attending clinical visits at MD Anderson, which generally requires high-quality insurance for access. Generalizability of our results are further limited by examining the demographic patterns among respondents vs nonrespondents in Study 1. Forty-one percent of the eligible survivors did not complete the questionnaire despite repeated contact by the study team; non-responders were significantly more likely to be Hispanic (p=.003), without a bachelor’s degree (p=.02), and of lower annual household income compared to respondents (p=.007). This is consistent with Rising et al.’s recent analysis of NCI’s 2018 Health Information National Trends (HINTS) population survey data showing that nonusers of personal mHealth technologies were more likely to be over the age of 65 and have lower incomes. [69] Given the challenge of sustaining patient engagement in mHealth technology, future research should target these patients who fit within the above demographic profiles. Finally, the sample sizes for Study 2 and 3’s on-patient testing were constrained by the need to complete all testing within one-week

periods, as the sensors were applied/tested by visiting engineers and not MDA 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.

Conclusion

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. User ratings of discomfort and difficulty were minimal, however, a significant minority of patients expressed concern with various aspects of the sensor's burden and its appearance.

Acknowledgments

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Conflicts of Interest: None

Abbreviations

OR: Odds Ratio

IMRT: intensity-modulated radiation therapy

MBS: modified barium swallow

FEES: fiberoptic endoscopic evaluation of swallowing

Post-RT: post end of radiation treatment

EMG: elecromyographical

Figure 1: Appearance of hypothetical and actual sensor prototypes

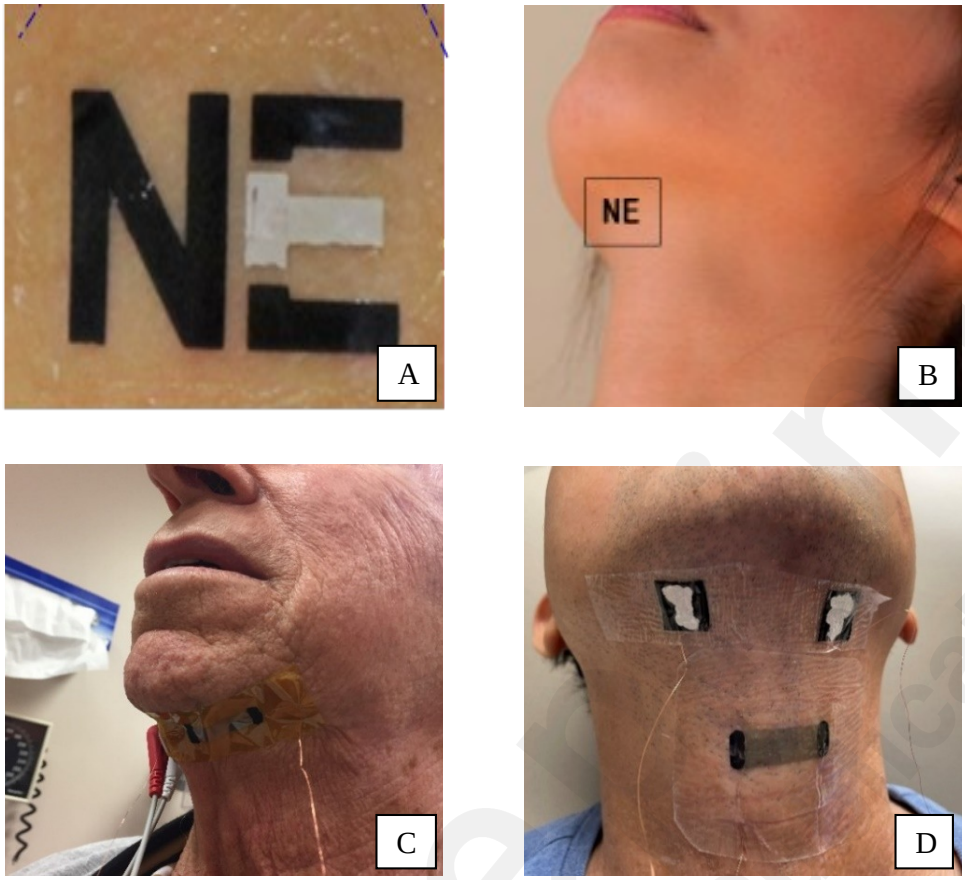


Figure 1. Panel A: Study 1 respondents were shown a photograph of the proposed sensor and its proposed location on the neck (Panel B). Panel C: Study 2's graphene strain sensor prototype, supported on polyimide tape 13 µm thick (contact surface is silicone), placed on the submental region probing muscle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

Figure 2: Recruitment CONSORT for Study 1 (n=138)

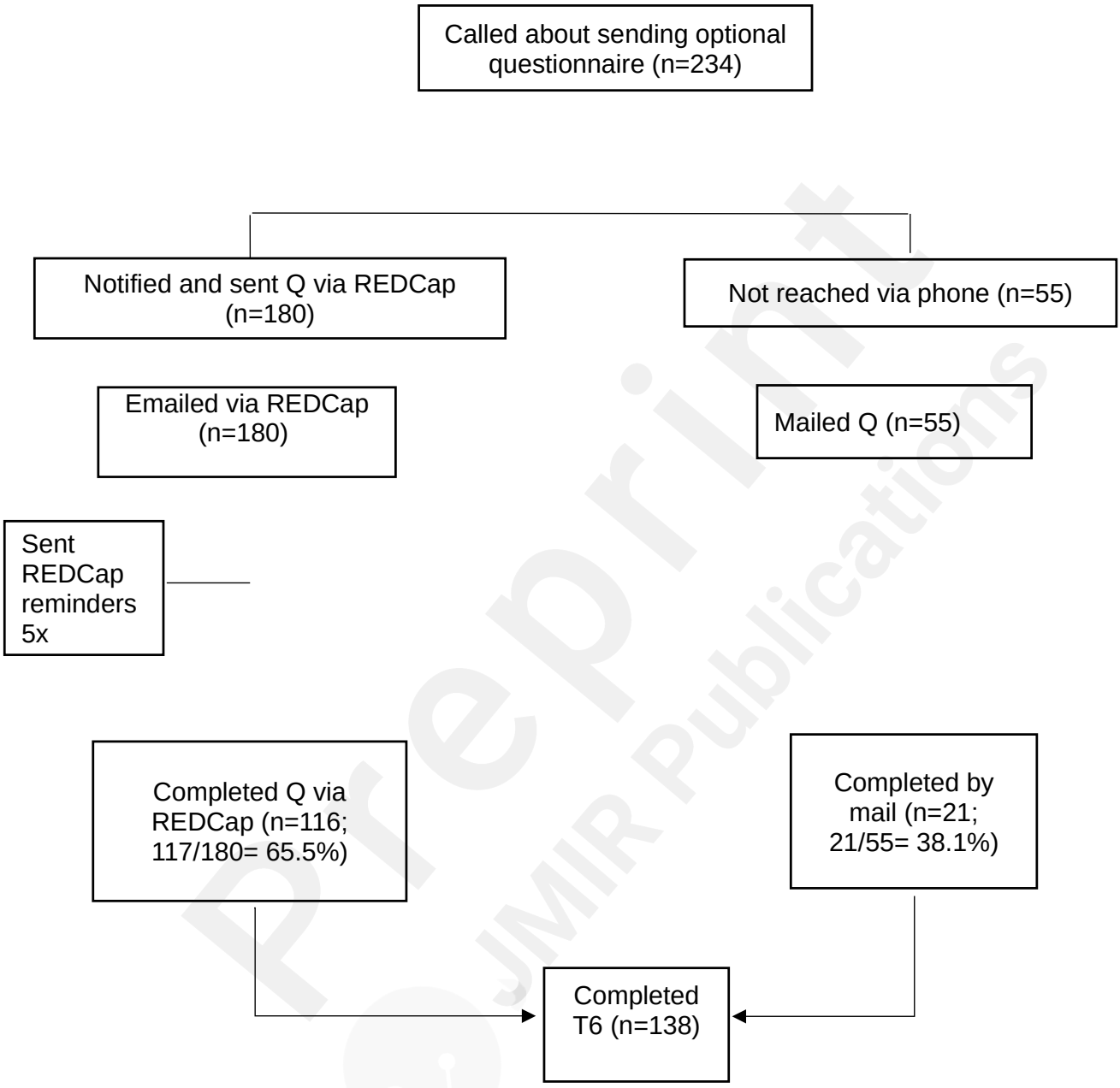


Figure 3: Recruitment Flowcharts for Study 2 (n=14)

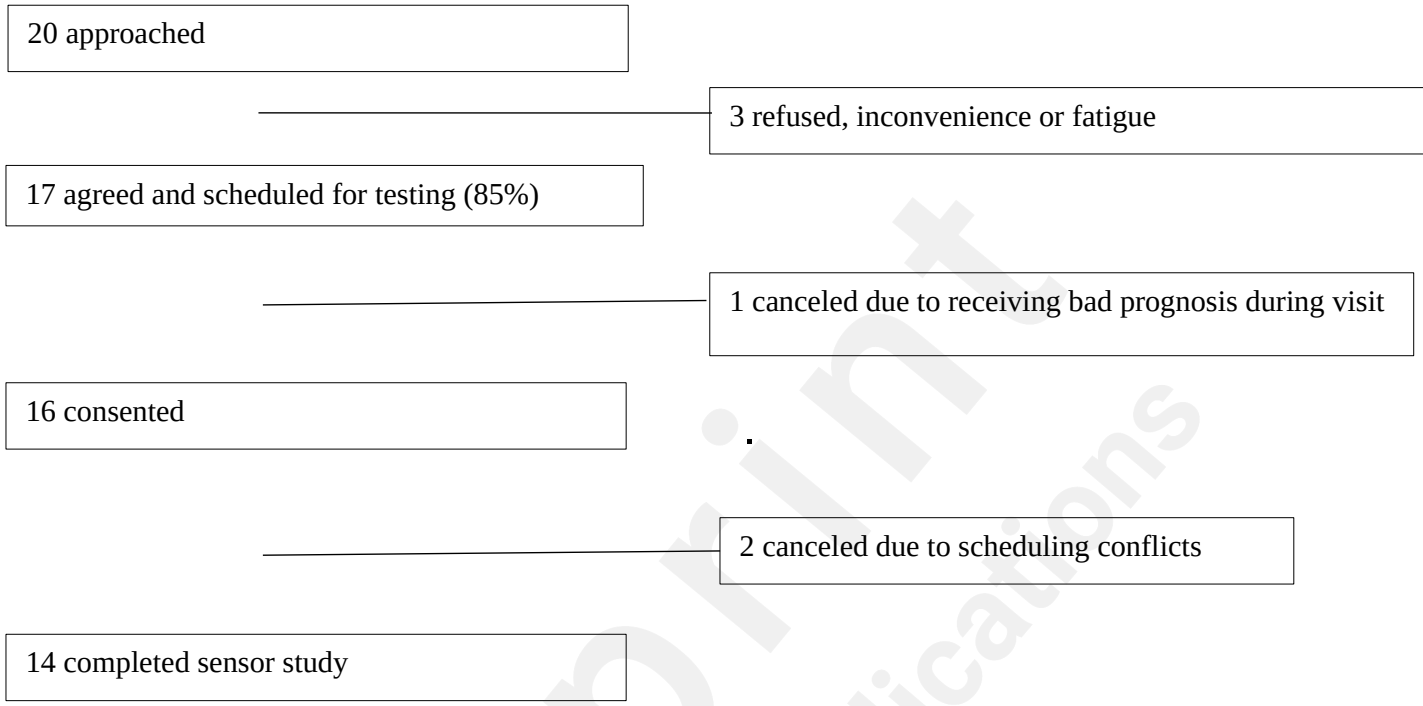
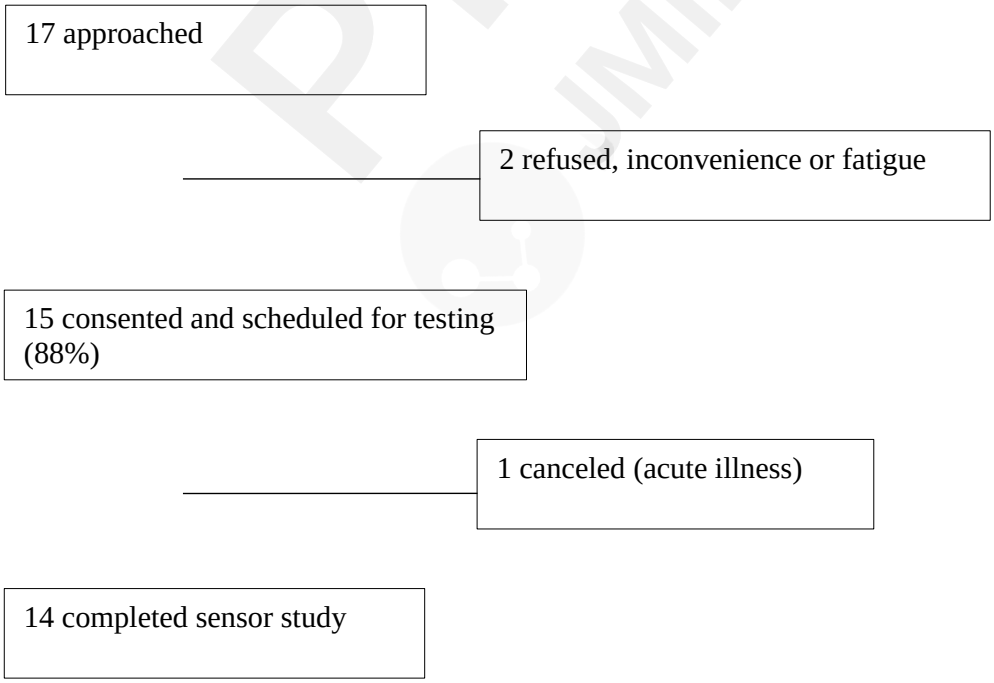


Figure 4: Recruitment Flowcharts for Study 3 (n=14)



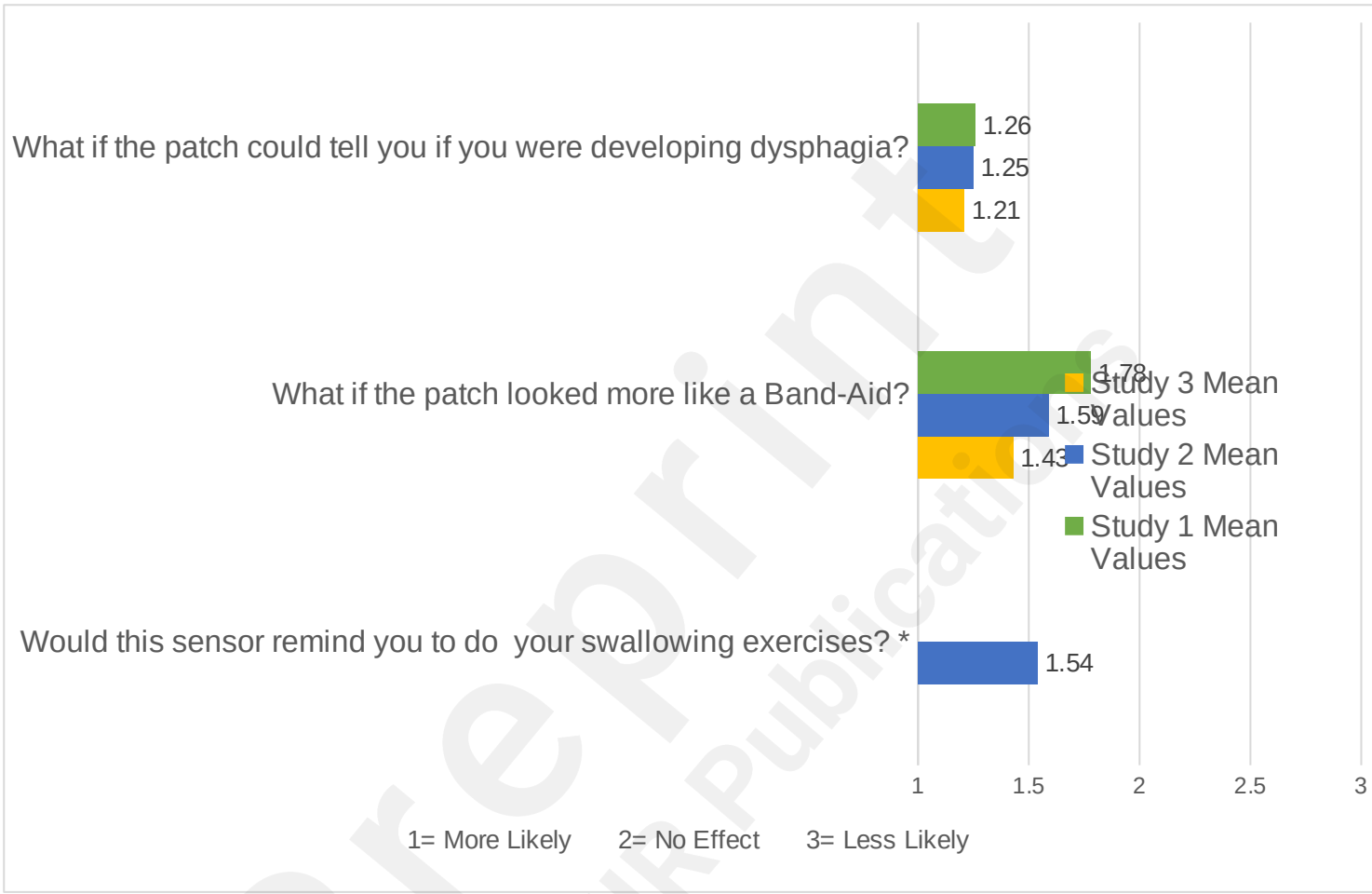


Figure 5. Studies 1-3: Design feature impact on user willingness 9 months

* Only participants in Study 2 (n=14) were asked these questions.

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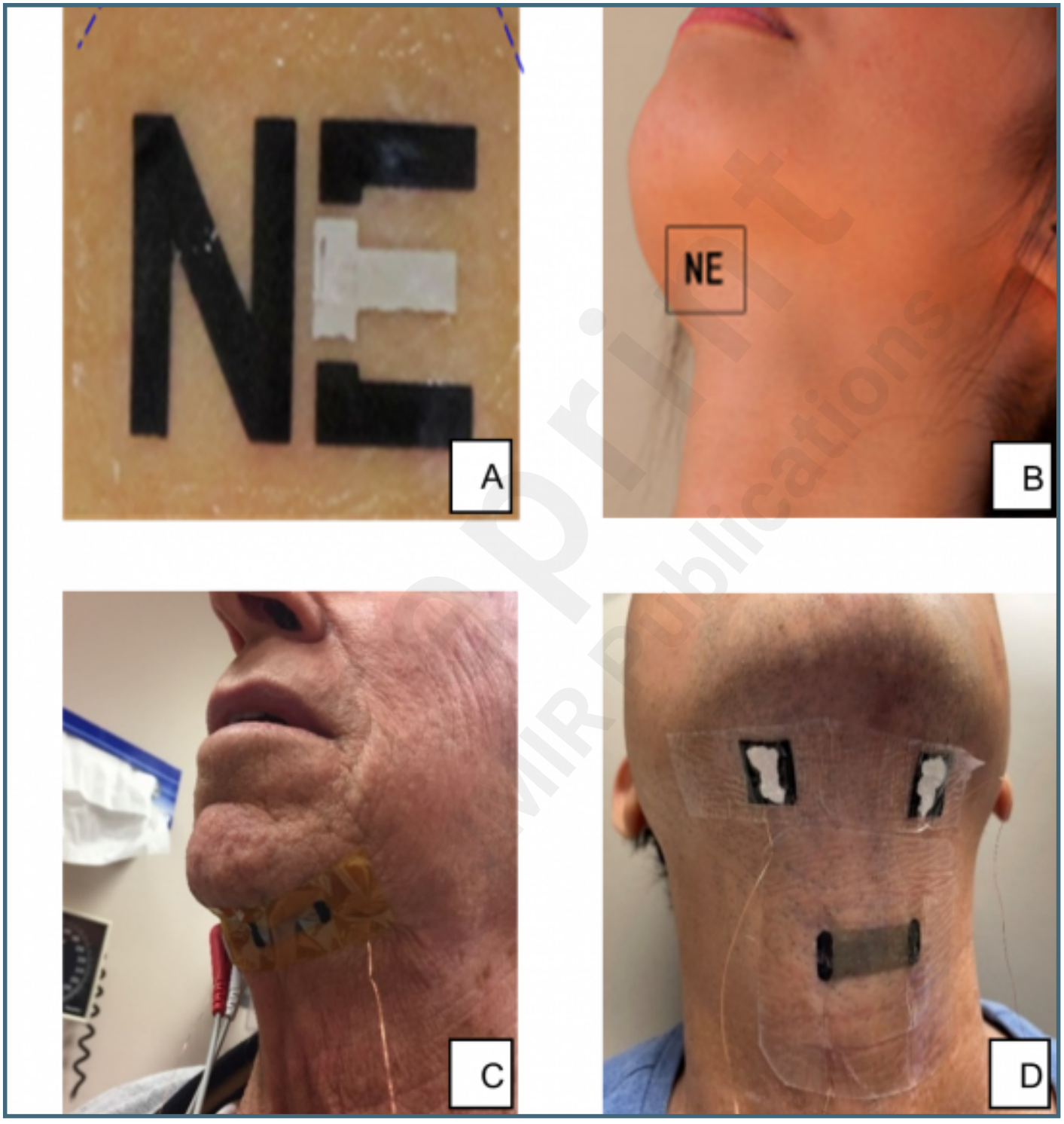
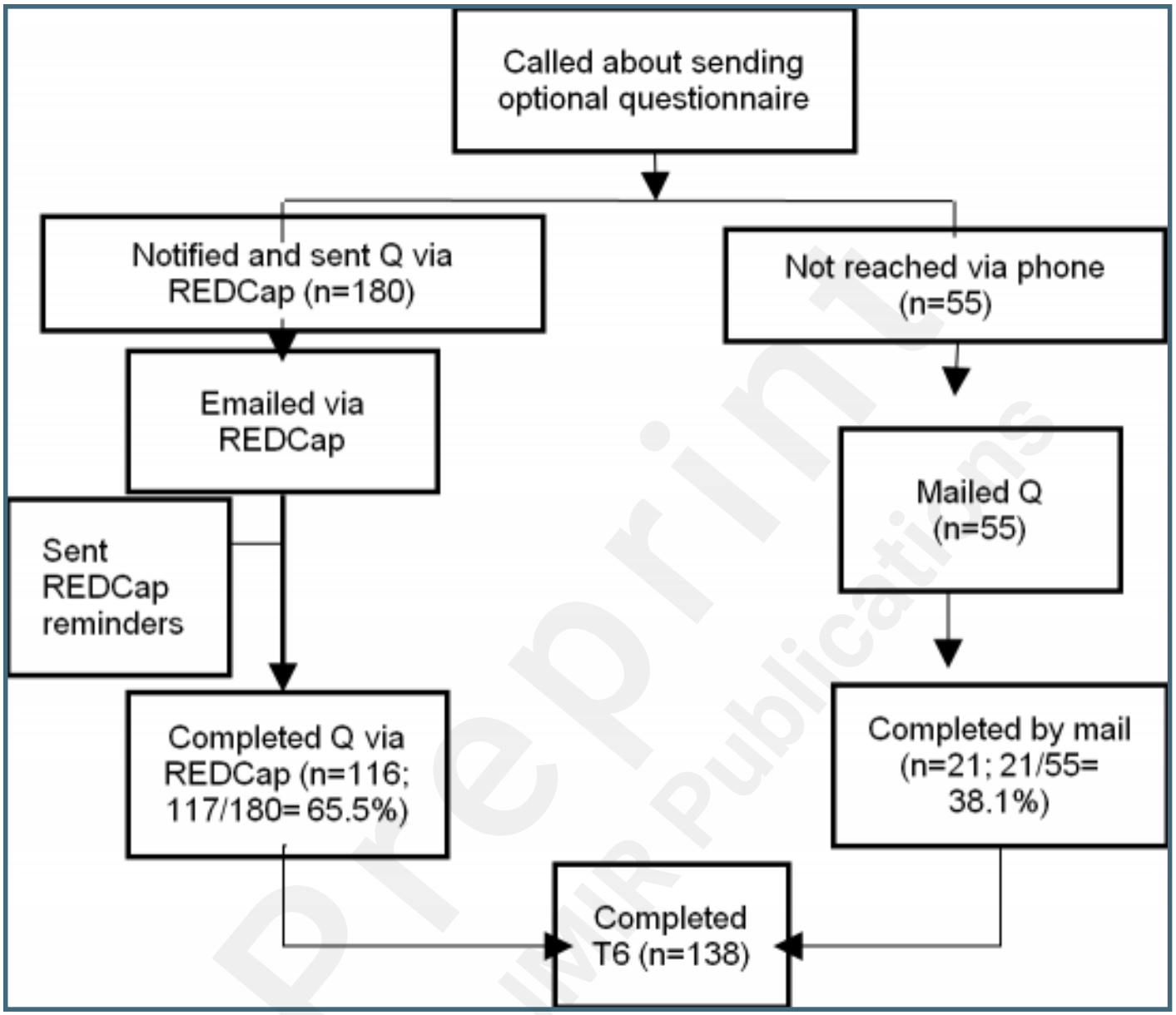
Supplementary Files

Figures

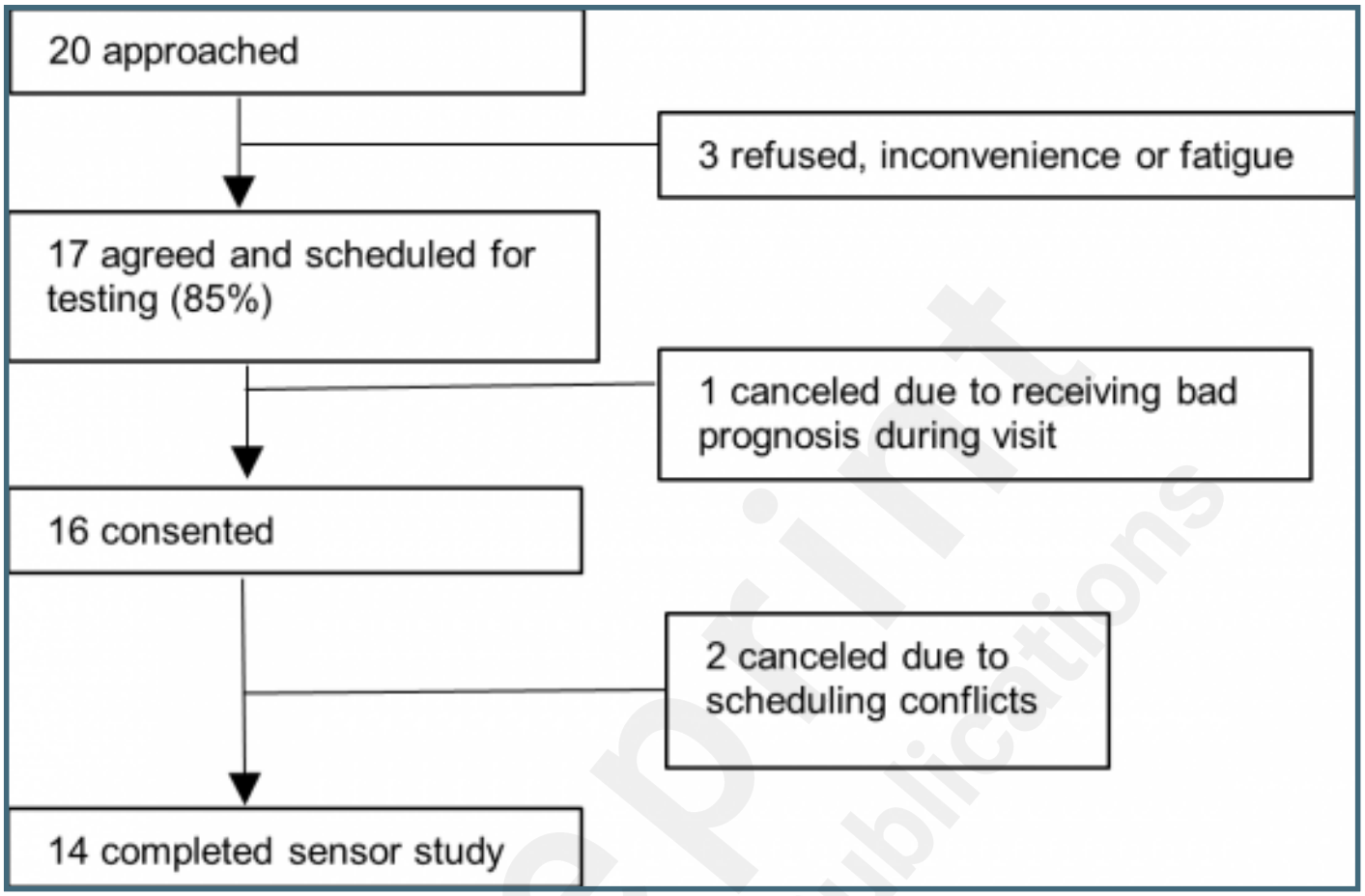
Panel A: Study 1 respondents were shown a photograph of the proposed sensor and its proposed location on the neck (Panel B). Panel C: Study 2's graphene strain sensor prototype, placed on the submental region probing muscle contraction. Panel D: Study 3's soft polymer strain sensor, now placed under the laryngeal prominence to capture movement during swallowing.



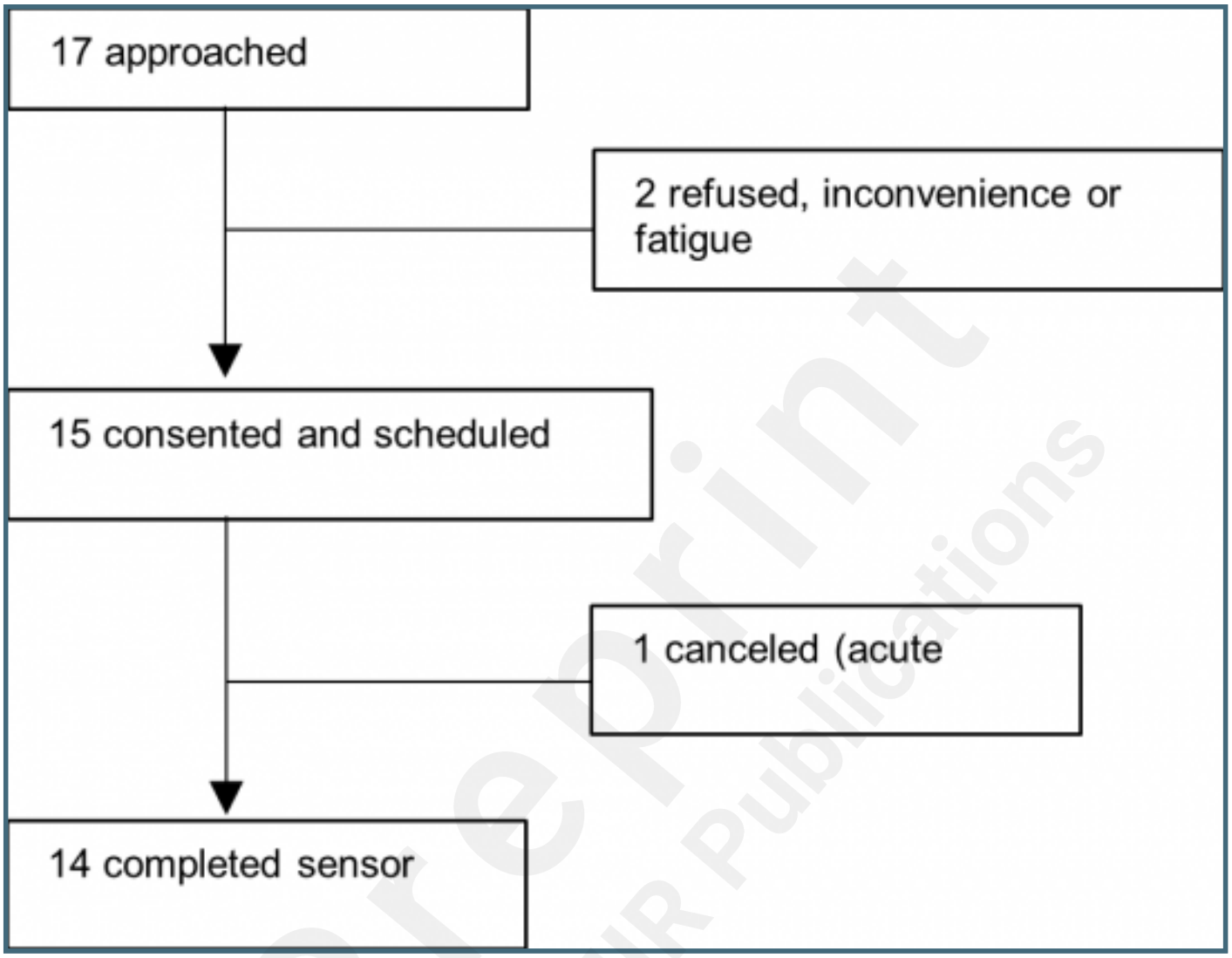
Recruitment CONSORT for Study 1 (n=138).



Recruitment Flowcharts for Study 2 (n=14).



Recruitment Flowcharts for Study 3 (n=14).



Studies 1-3: Design feature impact on user willingness 9 months.