Redesigning the Incentive Spirometer

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

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Abstract

The incentive spirometer (IS) is a plastic respiratory recovery device that helps prevent postoperative and respiratory complications. An IS can be prescribed to patients in the hospital and/or patients can be prescribed an IS to use at home. Using an IS helps keep your lungs inflated, healthy, and free of fluid. The goal of incentive spirometry is to inhale slowly for a while, which allows your lungs to fully inflate and prevent fluid buildup that can lead to pneumonia and atelectasis, for example. During the COVID-19 pandemic, COVID patients have been prescribed ISs to strengthen and maintain their lung health. However, despite the importance of using an IS in postoperative recovery and pulmonary illnesses, patient adherence is poor. Patients prescribed an IS are typically not monitored in hospitals or at home. Patient adherence may also be low because of the boring design of the standard IS. The goal of the Capstone project is to add a gamified component to existing IS designs to motivate patients to engage using IS. The chosen game is a ferris wheel ball scooper game that uses the force from inhalation to rotate a ferris wheel to scoop up small plastic balls into a collection bucket. After producing prototypes, we will ask volunteer patients among Family Medicine Inpatient Service at UVA Medical Center to compare our device to the standard hospital-given IS. They will be asked to fill out a detailed survey which will then be analyzed. We hypothesize that if we add a gamified component to the existing IS design, patient compliance and engagement will increase. We will evaluate several aspects of usage: how easy to use our device? How engaging is our device? And comparison of effectiveness of the two devices (ours and conventional) in terms of clinical deterioration during their hospital stay.

Introduction

The incentive spirometer (IS) is a plastic, non-electrical device that patients regularly use alone to practice fully inflating their lungs. This device is usually prescribed by physicians to patients recovering from surgeries around the abdomen or those with respiratory illnesses. Patients are instructed to inhale slowly and deeply into the device for around 15 minutes. Depending on their physician, usage of the IS can be prescribed up to once every two hours awake. While ISs have been proven to aid lung recovery, physicians do not typically monitor its usage, leading to patients forgetting or neglecting the IS.[1] Additionally, current IS designs are confusing and unengaging for many patients in hospitals.[2] This causes patients to not use the device without monitoring, resulting in slower respiratory recovery. **Therefore, the primary goal of this project is to develop a gamified version of the IS to improve patient compliance.**

Aim 1: Design and produce a prototype for a gamified IS

1.1. Transfer existing designs of ISs into computer-aided-design (CAD) software and incorporate a ferris wheel component. The IS CAD will be used for modeling and MakerBots for 3D printing.

1.2. Design and produce a prototype of a gamified version of an IS. Prototypes can be 3D printed, vacuum-formed, or produced in a variety of ways.

1.3. Manufacture a prototype that is cheap, engaging, intuitive, and incentivizes the patient to use the device without prompting from a physician.

Aim 2: Test the prototype

2.1. Test the prototype to ensure it is functional and will not pose any safety concerns – choking hazard for instance.

2.2. Write a fun instruction manual detailing how to properly use an IS to help encourage patient use.

2.3. Distribute both a standard IS and our playful IS to family medicine inpatient service patients at the University of Virginia (UVA) Hospital to obtain consumer feedback (what do the patients think of the design, do they think our IS is more engaging that the standard IS, do they prefer our IS or the standard IS) and collect data on patient usage (number of times daily patients used the IS). Also collect data on other patient factors and compare with previous studies to evaluate the importance of the following patient factors: instant reward/gratification, self-motivation, device proximity, patient perspective, and experience with IS use.[1]

2.4. Compare our device with the conventional IS and evaluate which device patients preferred and which one performed better based on consumer feedback and collected data on patient factors. Compare results to patient usage of a standard IS to determine if our engaging design improves patient compliance.

The proposed device will provide patients with a new and more engaging IS that will hopefully increase patient usage and compliance via self-motivation. Improving patient compliance is important since, like with other patient-administered therapies, patient adherence is critical to effective postoperative incentive spirometry.[1] The results of our study may have important implications in terms of patient factors that affect successful spirometry. Helping to improve patient compliance of IS use has the potential to help many postoperative patients who would greatly benefit from incentive spirometry.

Significance

The IS is used in a variety of different settings to help patient lung recovery. It is used for patients recovering from abdominal surgeries, chronic obstructive pulmonary disease (COPD), pneumonia, and many other respiratory illnesses.[2,3] Depending on the type of illness, a patient could be prescribed to use the IS from a few months up to their entire lives. Some patients are prescribed to use the IS every two hours.[4] With such frequent, repetitive use of the IS, many patients quickly stop after they are discharged from the hospital. Additionally, usage of the IS is not heavily emphasized after hospital discharge. Especially after a major surgery, patients are given a large amount of different medication, devices, and instructions. While the IS is important for healthy lung recovery, it can quickly be overshadowed by the large barrage of information. Therefore, a gamified version of the current IS can provide more enjoyment during usage, leading to higher voluntary use of the IS.

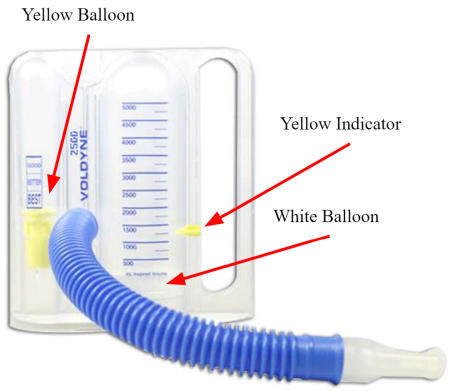

Figure 1: Existing incentive spirometer

Low Patient Compliance

A major concern for the current IS is low patient compliance. A study by Martin et al. studied IS patient compliance in different scenarios. 42 postoperative patients at the Rhode Island Hospital were prescribed with an IS as part of the hospital's standard postoperative care. 16 out of the 42 patients denied using the IS during their postoperative care even though the device was present in room.[5] The current IS designs contribute to the low patient compliance because they are unengaging and provide very little motivation for continued use. As seen in the existing IS design (Fig. 1), the only feedback the patient receives is the white balloon rising up to the yellow indicator and the smaller yellow balloon hovering between the "good," "better," and "best" labels on the side of the IS. This existing design offers almost no entertainment, so patients quickly lose motivation and interest in the device.

Unmonitored Usage

In many hospital postoperative care, a nurse or a physician will prescribe an IS, teach the patient to use the IS correctly, watch them use the IS correctly a few times, and then leave it up to the patient to continually use the IS. The nurses and physicians could tell the patient that they needed to use the IS for fifteen minutes every two hours, but it is up to the patient to keep themselves accountable. Especially with the current design being unengaging and not motivational, patients quickly forget to use the device.

Potential Impact of Solution

Our proposed solution will take into account literature research, patient complaints, and issues observed by our Capstone advisor, Dr. Masahiro Morikawa, to improve patient compliance through a gamified IS. Doing so will increase IS usage without the need of monitored usage and a quicker lung recovery for the patient. Especially if our proposed solution can double as a game, patients in the hospital will have one more source of entertainment available. With the current COVID-19 pandemic being a respiratory illness, a gamified IS would

be even more impactful, as an IS can be used by intensive care unit (ICU) COVID patients for inspiratory and expiratory muscle training.[6] COVID patients also may receive an IS upon discharge and/or an IS can be used at home to help strengthen the muscles that help you breathe.[7,8] The amount of patients in need of a lung recovery device has increased, and our proposed solution can help many of those patients.

Innovation

Prior Art

A variety of commercialized and patented ISs exist. Some past innovations of the IS include a game-based IS and a sustained maximal inspiration (SMI) IS. A 2010 patent for a digital, gamified version of the IS measures the inhaled or exhaled air flow rate and/or air volume and produces a corresponding electrical analog signal, which eventually is converted into a computer graphic such as a bird or superhero whose flying movement is controlled by the inhaled or exhaled air flow. The goal of the game is to keep the object between the designated minimum and maximum lines.[9] A 2015 patent for a new IS design utilizes three helical tubes to provide SMI exercises and is basketball-themed.[10] Despite the plethora of IS patents, most do not achieve commercialization, and even if they do, most hospitals still only use the conventional IS.

Some of the most recent IS designs include Breathacise® and InSee. Breathacise® is an IS with a built-in basketball game.[11] InSee is an auxiliary device that can be attached to an IS and reminds patients to use their spirometer, monitors how often they use it, and records how much air each breath is. A doctor can set a target tidal volume and frequency of use for a patient.[12,13] However, these IS products lack innovative designs and/or patient consideration. For instance, Breathacise® has the same overall design as a conventional IS (except for a basketball on top of the balloon) and InSee relies on a reminder system rather than the patient's self-motivation.

Proposed Solution

The proposed project seeks to create gamified and patient-oriented IS that is simple, intuitive, fun, and gives the user instant reward/gratification. Inspired by a ferris wheel and the water ring toss game, the current design is as follows: a ferris wheel-like structure will rotate as the user inhales. There will be small plastic balls resting at the base of IS. As the ferris wheel-like structure spins, it will pick up these balls and deposit them in a collection bucket. The goal is to transport the balls from the bottom of the IS into the collection bucket by inhaling for a sustained period of time (Fig. 2). Being primarily inspired by the water ring toss game, a retro game that is simple but engaging, the proposed concept aims to pique the user's interest and intrinsically motivate the patient to regularly use their IS. The design aims to be not so difficult that the user gives up, but also not so easy that the user gets bored and becomes less motivated to use it. Since the majority of patients using an IS are alone in their rooms for most of the day, self-motivation is an especially important factor to consider.

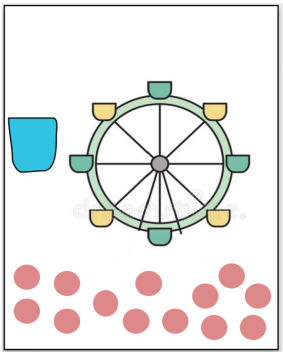

Figure 2: Schematic of the proposed project.

In support of our proposed project goals, a 2018 study developing digital games for respiratory therapy found that the participation of users in the design process is important for creating an effective product.[14] We will be able to collect patient feedback on our IS throughout

the design and production process thanks to Dr. Morikawa, who works at the UVA Hospital. Continuously receiving and implementing user feedback into our product will hopefully create a device with clinical value – a device that patients will enjoy and be motivated to use. The 2018 study also found that learning how to use the device should be easy and should not require a tutorial. Additionally, intrinsic motivation should be the goal.[14] All of these are goals of the proposed project.

Approaches

Team and Experience

Our team is composed of five undergraduate biomedical engineering students at the UVA: Danna Du, Shirley Zhang, Isabelle Talicuran, Paul Miranda, Theodore Vu. We have experience with medical device design, computer-aided design (CAD), 3D printing, and mechanical machinery from coursework, internships, and extracurriculars. We are working with Dr. Masahiro Morikawa, MD, MPH, the clinical director of UVA Family Medicine at the UVA Hospital. Towards the beginning of this project, we also worked with the Proto team, a team of undergraduates who, for their Capstone project, helped undergraduate students find research opportunities. The Proto team consists of Zack Landsman, Sarah Trans, and Aiden Houser.

Research and Development Strategy

In order to design an effective gamified IS, we will use the engineering design process of identifying the problem, brainstorming possible solutions, narrowing down the best possible solution, testing the solution, and repeating the necessary steps in between. A prototype of the gamified IS will be designed and produced to gather information regarding our prototype's design, engagement, and functionality.

Materials and Methods

Designing the IS

The overall design of our gamified IS closely mimics the original IS design (Fig. 1) in structure. Changes we made include removing the quantitative measurements, removing the "good, better, best" compartment, adding a gas flow indicator, and adding a ferris wheel with hollow balls in the main compartment, as seen in Fig. 3. The scoops of the ferris wheel were first created in CAD with a rectangular origami-inspired design to minimize weight (Fig. 4). A gas flow indicator was also designed in CAD to turn inhalation airflow into force that could rotate the ferris wheel (Fig. 5). As a patient would inhale into the gamified IS, they would inhale into a tube connected to the gas flow indicator, turn the pinwheel inside the gas flow indicator, rotate the gears connected to the gas flow indicator and ferris wheel, and in turn, rotate the ferris wheel to scoop up

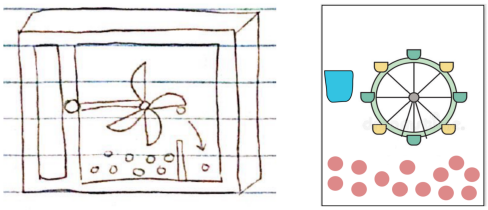

Figure 3: Gamified IS Design with Ferris wheel incorporation

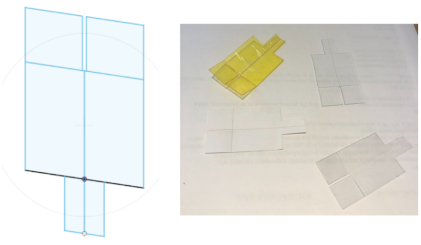

Figure 4: CAD and laser cut rectangular-origami scoops

the hollow balls.

Potential design themes for the gamified IS were also developed (Fig. 6). As a way to make the device more engaging, we developed 6 possible themes: Basketball, Snowman, Pokémon, Ice Cream, Fishing, and Mining. In addition to making the device more fun and colorful, some of these themes can add an element of difficulty. For example, the snowman theme adds a level of difficulty by requiring the balls to be collected in a certain order (head on top) to make a snowman. Because the balls are picked up by random, the snowman theme can increase patient usage as the patient tries multiple times to get a snowman to form from the individual balls.

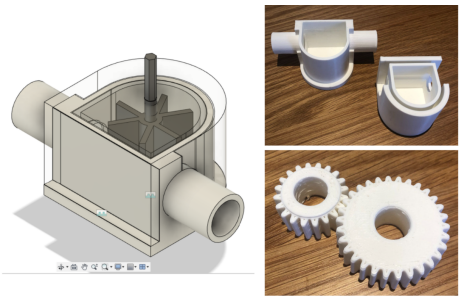

Figure 5: CAD and 3D printed gas flow indicator and gears

Figure 6: Potential gamified IS themes

Prototyping the IS

In order to manufacture a prototype of the gamified IS, a mixture of 3D printing, laser cutting, and vacuum forming was utilized. The primary reason why a mixture of different methods was used was due to the weight constraint of the IS. The force from inhalation is significantly less than the force from exhalation, so a priority during prototyping was ensuring that the materials used for each machine were as lightweight as possible due to the denseness of the PLA plastic used in the 3D printer. Therefore, only the gas flow indicator and gears were 3D printed as seen in Fig. 5. Projector lens filter sheets and Aliuka blank stencils (0.15mm) were used to laser cut the scoops of the ferris wheel (Fig. 4) and connected together with a styrofoam wheel connection piece. 20mm polypropylene hollow plastic balls were used to ensure that an inhalation force was enough to pick them up (Fig. 7). In preparation for the outer shell of the IS, we tested out a variety of different snap connections by first 3D printing a mold and then vacuum forming over the mold with white styrene thermoform plastic (Fig. 8). The outer shell of the IS will be made in a similar process of first producing a mold via 3D printing and later vacuum forming over the mold with clear PETG (polyethylene terephthalate glycol) plastic.

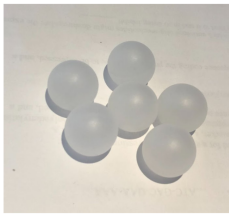

Figure 7: Hollow polypropylene balls

Figure 8: 3D print and vacuum form connection pieces

Design constraints, specifications, and assumptions

Progress made on prototyping the gamified IS was limited due to many different factors. This capstone project started during the spring of 2021 in the middle of the COVID-19 pandemic, which limited our resources when gathering materials, data, and finding advisors to guide us. The Biomedical Engineering (BME) department did not have the equipment (3D printer, laser cutter, and vacuum form machine) we needed at a consistent availability, so we manufactured our prototype in the Fabrications Lab (Fablab) at UVA's Architecture School . As a result of sharing machinery with the entire Architecture department, we struggled to find consistent availability of the 3D printers and laser cutters. Additionally, the prototype we envisioned was primarily made out of clear and thin plastic, but neither the Fablab facility managers, Fablab TAs, BME advisors, nor our capstone advisor were familiar with manufacturing with those types of materials.

Results

Due to the design constraints and limitations, we were unable to fully produce a prototype. Thus, we do not have a significant amount of results, as our results are dependent on the progress of our report. The data we have collected consists of a durability test of the 3D printed components and a survey comparing our gamified IS design to the standard, existing IS.

After conducting some preliminary drop tests to ensure the durability of our 3D printed components, we determined that the components were sufficiently durable as they did not break or crack under impact. The 3D printed components were dropped from table height (28-30 inches) multiple times to mimic a common scenario of a patient dropping their IS from tableside.

To preliminarily assess the success of our device, we sent out a survey to our peers and friends asking them to compare our device with the standard IS. In the survey, we asked the following questions:

1) As a patient, which device would you prefer to use more?
    a) Gamified Incentive Spirometer
    b) Current Existing Incentive Spirometer
2) On a scale of 1-10, how well do you think the gamified IS would perform in comparison to the current IS in terms of recovering lung health? Note: the main goal of the incentive spirometer is to be used frequently to fully expand a patient's lung.
    a) Rank from 1-10, with 1 being perform poorly and 10 being perform very well
3) On a scale of 1-10, how enjoyable would you think using the gamified incentive spirometer is as a patient?
    a) Rank 1-10, with 1 being not enjoyable and 10 being very enjoyable
4) As a patient, which incentive spirometer themes would you like best? Pick top 3 given figure 6:
    a) Basketball
    b) Snowman
    c) Pokémon
    d) Ice Cream
    e) Fishing
    f) Mining

We had a total of 13 respondents. 100% of the respondents reported that they would prefer to use our gamified IS over the standard IS. The average score for question 2 was 7.85±1.14, suggesting that most respondents think that our device will perform better than the standard IS. The average score for question 3 was 8.31±2.06, suggesting that most respondents think that our device will be enjoyable for patients to use. Concerning the last question, the Pokémon theme received the most votes. The Ice Cream theme had the second most votes, and the Basketball, Snowman, and Fishing themes all tied for third.

Discussion & Conclusion

Summary

We began our project in Spring 2021 by extensively researching prior art and patents. After confirming that there is a need for a redesigned IS, we began our designing process and settled on the final ferris wheel design after conferring with the Proto team, Dr. Shannon Barker, and Dr. Morikawa and some of his patients. Over the summer, we started the Institutional Review Board (IRB) process for our product and also started creating CADs for components we wanted to manufacture in the Fablab. This semester, we continued to make progress on Aim 1. The team, including our new team members, got trained on laser cutting and vacuum forming at the Fablab with the guidance of Melissa Goldman, the Fablab's facilities manager. We designed CAD models and were able to 3D print most components, including the gas flow indicator, gears, and snap connections of the outer shell (Fig. 9). We are now in the final stages of making our prototype and have a strong team who will continue our project next semester.

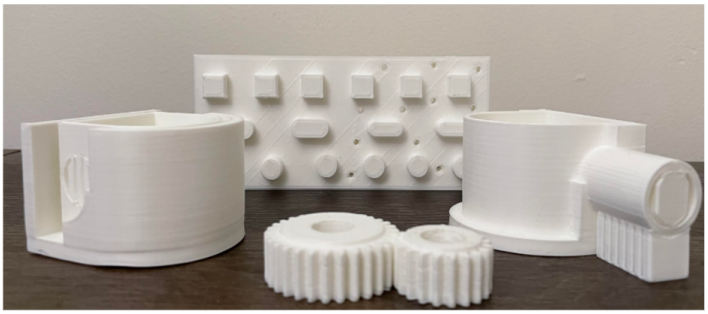

Figure 9: 3D printed gas flow indicator (left and right), gears (center front), and snap connections of the outer shell (center back)

Limitations

As previously mentioned, the main limitation of our project this semester was the lack of prototyping equipment, space, and material. Much of our rapid prototyping process relies on 3D printing and since we are working out of the Fablab at the Architecture school, we had to share the printers with the Architecture school students. Availability was never guaranteed since there are only six printers and they are first come first serve. Moreover, our rapid prototyping process was delayed by about a month because the Fablab was overwhelmed by all the projects the architecture students needed to complete and we were not able to receive the training needed to operate the machines until mid-October.

Another limitation of our project that delayed the prototyping process was having to recruit current 4th-year BME students during the end of summer and the beginning of fall to continue our project once we graduate in December. After recruiting for our project at the capstone fair this past August, we then spent the first half of September getting our new team members up to speed on our project and also introducing them to Dr. Morikawa.

One other limitation of our project was the abrupt transition to working on our project by ourselves after the Proto team graduated this past May. The Proto team connected us to Dr. Morikawa for our capstone and acted as mentors who gave us periodic feedback on our capstone project, helped determine what assignments we needed to complete, and helped communicate between us, Dr. Morikawa, and Dr. Shannon Barker (capstone II professor). However, after the Proto team graduated last May, we lost that support system and had to reach out to many professors (Dr. Timothy Allen, Melissa Goldman, Dr. Masahiro Morikawa, David Chen, Dr. Shannon Barker) to try to figure out our next steps.

Impact

Especially with the COVID-19 pandemic, the usage of incentive spirometers is more crucial than ever. By turning the current incentive spirometer into a ferris wheel game, our device will hopefully increase patient usage. As a device used during lung recovery to fully expand the lungs, the IS has an enormous impact on all the patients with and recovering from COVID-19. Additionally, our gamified IS can be used as a preventive care tool to help maintain lung health and prevent diseases, which is preferable to treating people after they get sick.

Future work

There is still much work to be done before achieving a polished end product. Our other team members – Paul Miranda, Isabelle Talicuran, and Theodore Vu – will continue working on our capstone project next semester. They will continue working on creating a functional prototype. Once a prototype has been made, they will perform functional testing on it, test it on themselves, and resume the IRB process with Dr. Sarah Blackstone (Research Program Advisor at UVA School of Medicine). After that, the prototype can be tested on Dr. Morikawa's Family Medicine Inpatient Service patients at UVA Medical Center in order to compare our device to the standard IS. The volunteer patients will be given a detailed Likert scale survey, which will then be analyzed to determine statistical significance between the standard IS and our device – Fig. 10 shows a preliminary survey that can be given to patients.

Age:
Gender:
Length of stay: _____ days
Primary discharge diagnosis:

Survey questions (All questions are asked 1-10 Likert scale)

1. On average, how many times did you use the device per day?
2. On average, how long did you use the device during each use (in minutes)?
3. How easy was the device to use?
4. How engaging/fun was the device to use?
5. How motivated were you to use the device?
6. Did you have a positive experience with the device?
7. How satisfied were you with the device overall?
8. How likely are you to use this device again?
9. I feel very confident using this device regularly to re-expand and clear your lungs?
10. How likely are you going to use this device regularly?
11. How easy is it to keep taking slow deep breaths using this device?
12. (only for the test group using the prototype) How difficult was it to scoop and deposit the balls?

Figure 10: Preliminary survey for volunteer patients

End Matter

Author Contributions and Notes / Acknowledgements

D.D. and S.Z. researched prior art, came up with designs, created CAD models, prototyped, and wrote the paper. D.D. began the IRB process for the project.

We would like to thank Dr. Masahiro Morikawa, MD, MPH for his continuous guidance, support, and encouragement throughout our capstone project. We would like to thank Melissa Goldman and Trevor Kemp at the Fablab for teaching us how to use the machinery and letting us use your workspace. We would also like to thank the Proto team (Zack Landsman, Sarah Trans, Aidan Houser), Dr. Shannon Barker, Dr. Timothy Allen, Noah Perry, Vignesh Valaboju, Dr. Caitlin Wylie, Dr. Richard Jacques, and Dr. Sarah Blackstone for their guidance and support throughout our capstone project and STS research.

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