



Factors in sustained compliance to a symptom-reporting mobile application: implications for clinical implementation

Warren R. Bacorro¹, Stephanie Ann Balid-Attwell², Paolo G. Sogono¹, Catherine Joy T. Escuadra², Cielito Reyes-Gibby³, Jocelyn C. Que^{4,5}, Teresa T. Sy Ortin^{1,6}

¹Radiation Oncology Department, University of Santo Tomas Hospital, Benavides Cancer Institute, Manila, Philippines; ²College of Rehabilitation Sciences, University of Santo Tomas, Manila, Philippines; ³Department of Emergency Medicine, Division of Internal Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX, USA; ⁴Center for Pain Medicine, Department of Anesthesiology, Faculty of Medicine and Surgery, University of Santo Tomas, Manila, Philippines; ⁵Pain Management and Palliative Care Unit, Benavides Cancer Institute, University of Santo Tomas Hospital, Manila, Philippines; ⁶Department of Radiological Sciences, Faculty of Medicine and Surgery, University of Santo Tomas, Manila, Philippines

Contributions: (I) Conception and design: TT Sy Ortin, JC. Que, WR. Bacorro, C Reyes-Gibby, SA Balid-Attwell; (II) Administrative support: TT Sy Ortin, JC Que; (III) Provision of study materials or patients: TT Sy Ortin, JC Que; (IV) Collection and assembly of data: TT Sy Ortin, JC Que, PG Sogono; (V) Data analysis and interpretation: WR Bacorro, SA Balid-Attwell, CJ Escuadra, TT Sy Ortin, JC Que, C Reyes-Gibby, PG Sogono; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Warren R. Bacorro, MD. Radiation Oncologist, University of Santo Tomas Hospital – Benavides Cancer Institute, España Boulevard, Sampaloc, Manila, Philippines. Email: warrenbacorro@gmail.com.

Background: The Internet-based Computerized Patient Assessment System (iComPAsS), a remote pain- and symptom-reporting application was developed to optimize pain monitoring and management. This sub-analysis sought to examine factors influencing compliance, to gauge the sustainability of its effects and to guide further development and implementation as part of usual care.

Methods: Patients ≥ 18 years old, with cancer and moderate-severe pain were randomized to standard pain management with pain diary or iComPAsS. Pain and symptom severity (using Edmonton Symptom Assessment Scale) and compliance (to iComPAsS or diary) were evaluated at week 0, 3, 6, 12 and 20. The Treatment Self-regulation Questionnaire (TSRQ), used to assess patient motivation, was administered at week 0, 6, 12 and 20. Pain levels and compliance were compared between the groups using Student's t-test. The Pearson Correlation Coefficient was used to examine the relationship between compliance and pain control, perceived competence in pain self-care, and Relative Autonomy Index (RAI).

Results: Out of 100 patients enrolled, 76 were included in the analysis (control; 37; iComPAsS, 39). Baseline pain levels and TSRQ characteristics were similar between the groups. Initial compliance and pain control at week 3 were significantly higher in the iComPAsS group. For the iComPAsS group, compliance directly correlated with uncontrolled pain and intrinsic motivation, and was more sustained compared to the control group.

Conclusions: The iComPAsS elicited rapid uptake and sustained compliance through intrinsic motivation. When adopting the iComPAsS for clinical use, patient baseline motivation levels may be assessed using the TSRQ, and depressive symptoms and other barriers to engagement must be identified.

Keywords: Telemedicine; symptom reporting; self-determination theory

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Introduction

The Internet-based Computerized Patient Assessment System (iComPAsS) is a telemedicine application that allows patients to report their pain and symptoms levels regularly so that the healthcare professional can manage them more efficiently, leading to better quality of life and functional outcomes. This shifts the paradigm of symptom management back to the cancer patient, fostering empowerment over his symptoms through the mobile application. Situated within the therapeutic relationship between the patient and the healthcare professional, the iComPAsS aims to capitalize on the intrinsic motivation of the patient by addressing the three elements defined in the self-determination theory (1) (Figure 1).

The self-determination theory, commonly used in intervention programs and in the development of technological advancements outside (2) and within the healthcare system (such as medication adherence, smoking cessation, weight management, and lifestyle change programs) (3-8), targets optimal motivation that is characterized by three important elements—autonomy, or self-regulation of behavior according to interest, values or satisfaction with the behavior itself, rather than external reinforcement; competence, or the sense of capability to achieve one’s goals or desired outcomes in optimally challenging situations; and relatedness, or the degree to which one feels connected to and understood by others. Integration of these elements in a program or tool results

in volitional or patient-initiated direction, which results in long-term and sustainable effects, compared to controlled-type motivation that is merely a result of pressure or demands from the healthcare professionals (8,9).

The iComPAsS was compared to usual pain care in a randomized clinical trial to evaluate its impact on pain control. The primary objective of this analysis was to examine the factors influencing patient compliance to a remote symptom-reporting mobile application use in order to gauge the sustainability of its effects and to help direct further development of the application and its eventual implementation as part of usual care.

Methods

Development of the mobile application

The iComPAsS, a tool for patient self-reporting of pain and symptoms, allows patients to report the severity of their pain and symptoms through the Internet using mobile phone, and physicians to view patient entries and send instructions back (e.g., to pick up a refill prescription or a revised prescription for purposes of dose titration, to follow-up in the clinic) and to generate graphical or statistical summaries (e.g., trend of pain over time from patient responses). A later design incorporated notifications that signaled patients to report at a frequency set by the physician based on the severity of pain, for purposes of dose titration.

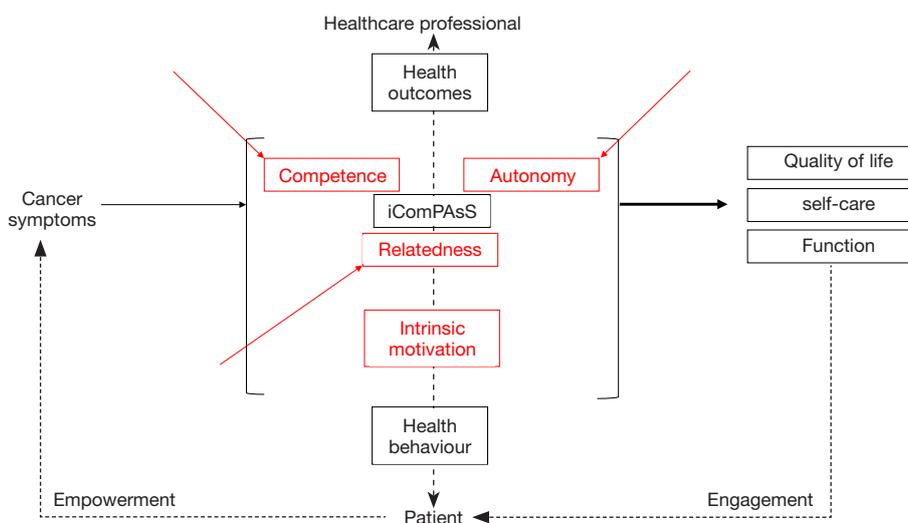


Figure 1 Conceptual framework.

Features of the mobile application

The Patient Interface is accessible from a mobile application, and is available in Android and iOS versions. The interface allows the patient to login, modify his username and password, access a menu, and log-out. The menu consists of the following options: *Profile*, *Prescriptions*, *MyTools*, *List of Doctors*, *Messages*, *Change Password* and *Help*. *Profile* allows the patient to view his demographic data and call the Pain Unit Hotline if data needs updating or correction; *Prescriptions*, to view physician instructions or prescriptions; *MyTools*, to access the Edmonton Symptom Assessment Scale (ESAS); *List of Doctors* to view a list of all his attending physicians, their specialties, schedules and office telephone numbers; *Messages*, to view instructions or messages from physicians and administrators; *Change Password* to change current password; and *Help* to access textual and a video tutorial on use, navigation and troubleshooting.

The Physician Interface allows the physician to login, modify his username and password, and access a menu, and log-out. The menu consists of the following options: *Profile*, *List of Patients*, *Messages*, *Change Password*, and *Help*. *Profile* allows the physician to view his profile (schedule, contact numbers, specialization) and to contact the administrator for necessary updates or corrections; *List of Patients*, to view a list of his patients, access their individual records (such as demographic data, clinical data, other attending physicians, and responses to ESAS or other tools); *Messages*, to view messages that he has sent to patients or coming from administrators, and to send messages to patients, such as reminders, instructions, prescriptions, and appointment schedules; *Change Password* to change current password; and *Help* to access textual and a video tutorial on use, navigation and troubleshooting of the application.

Trial design

The iComPAS was compared to standard care in a parallel, randomized controlled trial. From April 2016 to May 2017, patients fulfilling the following criteria were recruited and included in the study: at least 18 years old, cancer diagnosis, pain score ≥ 4 on the Visual Analogue Scale, access to an Android or IOS phone, willing to learn and use a telemedicine application for symptom reporting, and no evidence of cognitive impairment or psychopathology. Recruitment of at least 33 patients on each arm was targeted. A written informed consent form was obtained.

Participants were randomized to either the standard care arm or the iComPAS in a 1:1 ratio, thus allowing detection of statistical significance with the smallest number of participants. Cluster randomization at the physician level was done to reduce the risk of experimental contamination and, to achieve a better group balance, minimization, a form of adaptive randomization, was employed, using the following factors: sex, stage of disease, and payer status (charity case versus self-pay).

At our institute, standard pain management, as defined in the USTH BCI Policy Manual and the USTH Pain Management and Palliative Care Unit Procedural Manual, the registered pain nurse initially assesses the patient, using tools such as the ESAS along with other relevant health outcome or quality-of-life questionnaires. The findings are discussed with a pain management specialist, who then takes a medical and psychosocial history and conducts a directed physical examination. Patients presenting with complex problems are seen in a multidisciplinary meeting with other health care professionals (such as medical oncologist, radiation oncologist, surgical oncologist, orthopedic surgeon, palliative care specialist, clinical psychologist, nutritionist, rehabilitation specialist, occupational/physical therapist) based on the needs of the patient and his family. In the absence of the need for hospitalization, patients are seen on an outpatient basis at the Pain Clinic. Members of the pain management and palliative care team are accessible to patients 24/7 by phone. The management of the interdisciplinary team is guided by the pain management and palliative care guidelines established by the National Comprehensive Cancer Network (10).

The control arm consisted of standard pain management, pain diary that is accomplished once daily, and daily Pain Unit nurse call when pain score ≥ 7 until controlled (score ≤ 3). The intervention arm consisted of usual pain management and iComPAS. Patients were followed up within 20 ± 2 weeks from enrolment. Follow-up consisted of a clinic visit and questionnaires at baseline and at week 3, 6, 12 and 20.

The nature of the iComPAS precludes blinding of the patient and physician. The research staff conducting the study assessments were different from those who conducted the randomization and were not allowed ask the patient about the iComPAS.

Outcome measures

The Edmonton Symptom Assessment Scale (ESAS) is a

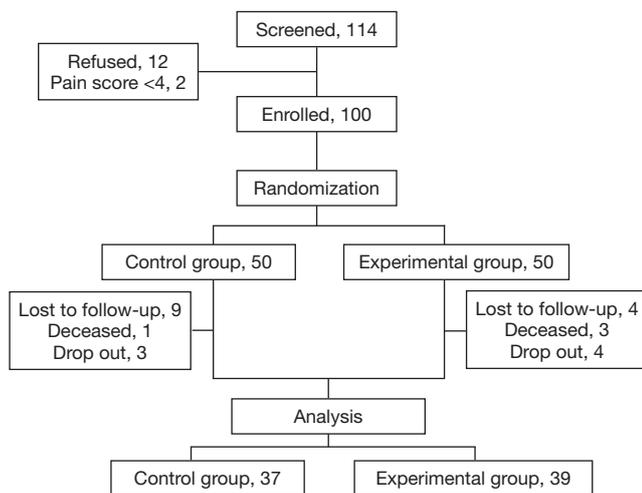


Figure 2 Final sample size included in analyses.

simple, validated tool that was originally developed for screening and monitoring for the most common symptoms in patients with cancer. The ESAS uses a 0–10 numerical scale (0 is none, 10, worst) for symptoms including pain, fatigue, drowsiness, nausea, anxiety, depression, quality of appetite, dyspnea, sense of well-being, and one other symptom chosen by the patient (11). For our purposes, a pain score of 7–10 was severe, 4–6, moderate, 1–3, mild and 0, none (10). Controlled pain was defined as no or mild pain.

Compliance rate was defined as the percentage of patients who have adhered to the prescribed frequency of symptom-reporting, and was in four one-week tracking periods (week 3, 6, 12 and 20).

The Treatment Self-Regulation Questionnaire (TSRQ) was employed to measure the effect of the self-determination theory. The TSRQ consisted of a Perceived Competence Scale (PCS) for Pain Management, to gauge perceived capability for self-care; a Pain Management Questionnaire, to explore motivation behind compliance to pain medications and treatment; and a Program Participation Questionnaire, to explore motivation behind enrolling and continuing the symptom-reporting program. Responses are given using a 7-point Likert scale. Subscale scores are then derived to assess different forms of motivation: amotivation, external, introjection, identification and integration (12). The TSRQ was administered at baseline, week 6, 12 and 20.

Statistical analysis

Pain levels and compliance were compared between the

groups using Student's *t*-test. The Pearson Correlation Coefficient was used to examine the relationship between compliance to symptom-reporting and (I) pain control, (II) perceived competence in pain self-care, and (III) nature of motivation (intrinsic versus controlled-type) behind adherence to pain medication/treatment and entry to and continuation of participation in the symptom-reporting program. A correlation coefficient of 0.00–0.19 is considered very weak; 0.20–0.39, weak; 0.40–0.59, moderate; 0.60–0.79, strong, and 0.80–1.00, very strong (13).

Ethics statement

This study was reviewed and approved by the University of Santo Tomas Hospital—Institutional Review Board (IRB-MD-04-2015-054-A1).

Results

Out of 100 enrolled participants, 13 were lost to follow up, four died, and seven opted to drop out after controlled pain; 76 were included in this analysis—37 from the control arm and 39 from the experimental arm (*Figure 2*). The majority are female, married, with college degree, unemployed, with an annual income under USD 2,000, or living with family. There are no significant differences between the two arms in terms of demographic characteristics (*Table 1*).

Baseline pain level (pain score 5.09) and self-regulating characteristics—perceived moderate competence for pain self-management, predominantly intrinsic motivation scores for adhering to pain medications/treatment and entering the symptom-reporting program [as indicated by moderately high Relative Autonomy Index (RAI) values]—were similar between the two groups (*Table 2*).

Overall compliance to symptom-reporting was significantly higher for the experimental arm (*Table 3*). At any point, compliance was higher for the experimental arm, and significantly so during weeks 3 and 12. Peak compliance rate was 64% in the experimental arm, observed at week 3 (first tracking period), compared to 38% in the control arm, at week 6 (second tracking period). Finally, low compliance (less than 20%) was observed in both arms at week 20. Percentage of patients with controlled pain was significantly higher (1.4 times) in the iCompAsS group compared to the control group at week 3.

For other symptoms, including anxiety and depression, severity levels at baseline and throughout the course of the study were mild and generally stable (*Table 4*).

Table 1 Demographic characteristics

Variables	Control group (N=37), n (%)	iComPAsS group (N=39), n (%)	P value
Age (mean ± SD)	57.85±12.64	54.82±15.70	0.35
Sex			0.49
Male	17 (45.95)	15 (38.46)	
Female	20 (54.05)	24 (51.54)	
Marital status			0.45
Single	5 (13.51)	7 (17.95)	
Married	24 (64.86)	24 (61.54)	
Common law partner*	1 (2.70)	1 (2.56)	
Widowed	1 (2.70)	–	
Separated	6 (16.22)	7 (17.95)	
Educational attainment			0.95
Primary	4 (10.81)	4 (10.26)	
Secondary	11 (29.73)	9 (23.08)	
College	20 (54.05)	23 (58.97)	
Graduate	1 (2.70)	2 (5.13)	
Doctorate	1 (2.70)	1 (2.56)	
Religion			0.67
Catholic	31 (83.78)	32 (82.05)	
Non-Catholic	6 (16.22)	7 (17.95)	
Occupation			0.34
Employed	9 (24.32)	7 (17.95)	
Self-employed	5 (13.51)	1 (2.56)	
Housewife	1 (2.70)	3 (7.69)	
Unemployed	17 (45.95)	23 (58.97)	
Retired	5 (13.5)	5 (12.82)	
Annual Income			0.52
<USD 2,000	21 (56.76)	26 (66.67)	
USD 2,000–4,000	4 (10.81)	1 (2.56)	
USD 4,00–8,000	3 (8.11)	3 (7.69)	
>USD 8,000	–	1 (2.56)	
No answer	9 (24.32)	8 (20.51)	
Living conditions			0.59
Alone	1 (2.70)	1 (2.56)	
With family	32 (86.49)	33 (84.62)	
With carer	4 (10.81)	4 (10.26)	
No answer	–	1 (2.56)	

In the iComPAsS group, compliance positively correlated, although weakly, with uncontrolled pain (0.33) and an intrinsic motivation for entry into the program (0.25) and for continued program participation (0.28). None of the factors significantly correlated with compliance in the control group (*Table 5*).

Discussion

Self-determination theory is an effective theoretical basis for various intervention and prevention programs. This analysis examined how the theory applies to a mobile application designed to permit remote symptom-reporting towards optimized pain and symptom monitoring and management and eventually, improved health-related outcomes.

In both groups, patients had high RAI values (intrinsic motivation) (*Table 2*) and the manner of introduction of the pain diary and the mobile application were similar, and included a detailed orientation on the rationale (thus addressing the autonomy element) and the use of the tools (thus addressing the competence element). However, compliance during the first tracking period (week 3) was significantly (2.5 times) greater for the iComPAsS group than for the control group (*Table 3*), reflecting a quicker uptake of the mobile application. While this may partly relate to our inclusion criteria (mobile phone access and willingness to learn and use a telemedicine application), the incorporation of a video tutorial and a *Help* function in the application, likely enhances adoption of the technology by further addressing the competence element.

The higher uptake rate in the experimental arm was associated with a significantly higher percentage of patients with controlled pain (49% versus 69%, in favour of iComPAsS, $P=0.02$) and thus a shorter time to pain control. This affirms the clinical utility of a remote symptom-reporting tool, facilitating more efficient pain management.

The subsequent tracking period showed an upward trend (+44%) for compliance in the control arm, and the reverse (–24%) for the iComPAsS, reflecting the effect of pain control on compliance. During this period, there was an associated increase in the percentage of patients with controlled pain in the control group, and a stable trend in the other. The third tracking period saw a significant drop (–50%) in compliance in the control group, suggesting compliance driven largely by lack of pain control than intrinsic motivation. The drop is less significant (–24%) for the iComPAsS arm, suggesting sustained compliance that is driven by intrinsic motivation. Thus, in the iComPAsS

Table 2 Baseline pain level and self-regulating characteristics

Clinical variable	Control (mean ± SD)	iComPAsS (mean ± SD)	P value
Pain level	5.09±1.11	5.09±1.56	0.99
Self-regulating characteristics			
Perceived competence for pain self-management	4.38±1.04	4.43±1.40	0.84
Adherence to pain medications/treatment			
Autonomous regulation	5.49±1.28	5.77±1.22	0.32
Controlled regulation	4.82±1.19	4.95±1.57	0.69
Relative Autonomy Index	0.67±0.75	0.83±1.25	0.52
Entry into the symptom-reporting program			
Autonomous regulation	5.59±1.27	6.04±1.77	0.10
Controlled regulation	4.41±1.34	4.51±1.77	0.78
Relative Autonomy Index	1.17±1.26	1.52±1.61	0.30

Table 3 Compliance to symptom-reporting schedule and pain control

Tracking period	Compliance			Pain Control		
	Control, mean ±SD (%)	iComPAsS, mean ±SD (%)	P value	Control (%)	iComPAsS (%)	P value
Overall	19.92±25.48	34.09±23.34	<0.01			
3rd week	26.12±35.56	64.29±28.04	<0.01	49	69	0.02
6th week	37.71±50.27	48.81±31.30	0.24	71	68	0.70
12th week	19.11±32.67	36.88±32.06	0.02	72	69	0.83
20th week	11.61±31.02	15.57±24.96	0.54	78	65	0.43

arm, uncontrolled pain and sustained intrinsic motivation both correlate with continuing compliance to the program. This sustained intrinsic motivation may be attributed to the provision of real-time *Notifications* in the iComPAsS, which addresses the relatedness element more effectively than the daily nurse calls in the control group.

By better incorporating features that address all three elements of the self-determination theory, the iComPAsS was able to elicit a more rapid initial uptake, to achieve the desired clinical effect more promptly, and to effectuate a more sustained compliance, when compared to the control group. If it is to be introduced as part of standard practice, these features need to be identified, maintained and reinforced. The following recommendations for each element are two-fold, and directed to the application and to the healthcare professional.

Autonomy-supportive elements, which create a conducive environment that would assure the patient that he is

understood, regarded positively and unconditionally, and permitted to work at his own pace, are key (14). The patient must be presented a clear rationale for the recommended behavior (symptom reporting), a clear mechanism of the process (how symptom reporting might lead to a more efficient symptom management and improved health outcomes), and an assurance that he is regarded as an important player in the process (15,16). These will foster a sense of ownership, commitment and active involvement (17). While these have been addressed in the conception and design of the iComPAsS (by providing a video tutorial and a *Help* section), presentation of the application as a tool rather than a task was as important and should be done separately from the tutorial for its use. Framing that the mobile application is a device that listens, offers alternatives and make things easier and more practical for the patient addresses the autonomy element of motivation. This will ensure continued use of the application.

Table 4 Pain and symptom severity through time

Symptom	Baseline	3rd week	6th week	12th week	20th week	P value
Control						
Pain	5.09±1.11	3.72 +2.60	2.62±3.10	2.32±2.79	2.00±2.88	<0.01
Tiredness	2.44±2.47	1.74±2.04	1.22±1.98	0.75±1.46	1.43±1.99	<0.01
Drowsiness	2.05±2.33	1.62±2.03	1.32±2.17	1.25±1.96	1.29±1.97	0.20
Nausea	1.02±2.15	0.79±1.79	0.22±0.89	0.14±0.76	0.14±0.53	0.05
Lack of appetite	2.23±2.94	1.95±2.47	1.03±2.03	1.50±2.44	0.71±1.27	0.05
SOB	0.95±2.02	0.79±1.59	0.55±1.19	0.64±1.22	1.14±1.79	0.60
Depression	1.58±2.18	1.03 +1.75	0.51±1.33	0.75±1.51	0.79±2.15	0.01
Anxiety	1.60±2.40	0.72±1.89	0.62±1.57	0.75±1.46	0.71±1.90	0.41
Poor well-being	3.53±2.02	2.87±1.82	2.14±1.87	2.46±2.27	2.21±1.48	<0.01
iComPAsS						
Pain	5.09±1.56	2.58±2.24	2.71±2.57	2.66±2.38	2.77±2.78	<0.01
Tiredness	2.84±2.92	1.53±1.96	1.64±2.08	1.72±2.07	1.32±1.84	0.05
Drowsiness	1.82±2.69	1.19±1.74	0.95±1.53	1.31±2.01	1.59±1.87	0.23
Nausea	0.64±1.38	0.28±0.91	0.67±1.83	0.50±1.02	0.27±0.88	0.51
Lack of appetite	2.02±2.65	1.12±1.76	1.74±2.43	1.75±2.54	1.73±2.07	0.29
SOB	1.02±2.04	0.33 +0.92	0.57±1.29	0.88±1.90	1.00±1.41	0.22
Depression	2.16±3.05	1.02±1.88	1.45±2.15	1.09±2.23	0.91±1.80	0.05
Anxiety	1.84±2.70	1.07 +1.92	1.45±2.21	1.25±2.24	0.77±1.74	0.27
Poor well-being	3.51±2.38	2.33±1.69	2.67±2.18	2.50±1.76	2.41±1.84	<0.01

Table 5 Correlation between compliance to symptom-reporting and pain and TSRQ domains

Factor	Association with compliance (Pearson correlation coefficient)	
	Control	iComPAsS
Uncontrolled pain	0.13	0.33
Perceived pain management competence	-0.17	-0.20
Relative Autonomy Index		
Entry into symptom-reporting program	0.14	0.25
Adherence to medications/treatment	-0.15	0.18
Continued program participation	0.16	0.28

For the competence element, it is recommended that informational resources on skills and knowledge on symptom management, supportive tools for behavioral implementation, and feedback mechanism in the forms of reminders and brief reports for the patient's progress be

included in the final version of the application (18). The healthcare professional should provide relevant information about the patient's current condition, symptoms, treatment, and prognosis in a timely manner. This will foster in the a patient a sense of being in control and reduce anxiety.

Autonomous disengagement entails allowing the patient for an educated decision on whether to report their symptoms or not and to choose a medium that is relevant to them at a given moment. Thus, they should be given access to all available platforms, such as the traditional face-to-face and electronic mobile format. The advantages and disadvantages of one over the other must be discussed collaboratively with the patient. Thus, the patient may anticipate or report any barriers in the use of the mobile application and, together with the healthcare professional, find potential ways to address them.

For the relatedness element, social support within the context of cyberspace such as provision of web blogs, bulletin board systems or just an easy access to community online or the healthcare professional may be included (18). A strong feedback mechanism must be put in place that will reinforce symptom-reporting behavior, address negative comments about the application or symptom management in general. Timely response from the healthcare professional is key and combining personal and electronic approaches during the first sessions with the patient might be valuable. Patients prefer a stronger therapeutic relationship with their healthcare professionals so introducing them to mobile application and completely removing the personal meetings will not be very effective. Feedback must also be provided in a non-controlling language, with provision of choices and coupled with verbal explanations to help them understand the process better. In this manner of presentation, the patients would participate more actively.

On the other hand, it must be noted that our cohort had moderately high baseline levels of intrinsic motivation and mild levels of accompanying symptoms, which remained generally stable throughout the follow-up. In general, drop-out rates increase through time in several studies that employ technology as a platform compared to face-to-face meetings. When implementing this in clinical practice, it might be useful to use the TSRQ to gauge the baseline levels of motivation of the patient, and to screen for other factors that might hamper engagement, such as depressive symptoms, which are common among cancer patients especially those with severe or debilitating pain (19). These information could direct the healthcare practitioner to employ adjunct measures that can enhance uptake and sustained compliance, or an alternative, better suited approach.

Finally, compliance was largely influenced by uncontrolled pain, and despite a relatively sustained compliance consistent with intrinsic motivation in the iComPAsS group, it must be noted that after about three

months of use, compliance has consistently declined despite lack of further increase in pain control. This might suggest that for the patient, the utility of this tool is limited to the early stages of pain management (initiation and dose titration) rather than for longer-term pain and symptom monitoring. Currently, an enhanced version of the app is being developed to cater to cancer patients with acute pain and patients with pain in the perioperative period.

Conclusions

By successfully addressing all three elements of the self-determination theory, the iComPAsS program is able to elicit a more rapid uptake, to achieve the desired clinical effect promptly, and to effectuate sustained compliance through intrinsic motivation. Uncontrolled pain and sustained intrinsic motivation correlate with continuing compliance to the program.

When adopting the iComPAsS for clinical use, the TSRQ may be employed to gauge baseline motivation levels, and patients must be screened for barriers to engagement, such as depressive symptoms, which are common among cancer patients. These information could direct the healthcare practitioner to employ adjunct measures that can enhance uptake and sustained compliance to the program, or an alternative, better suited approach.

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Footnote

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <http://dx.doi.org/10.21037/jhmhp.2018.04.01>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was reviewed and approved by the University of Santo Tomas Hospital—Institutional Review Board (IRB-MD-04-2015-054-A1). A written informed consent form was obtained.

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