Collection of timeseries of appetite-related sensations using a handheld computer: a case study

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ABSTRACT: We present a case study in the design and subsequent use of ”OKMO”, a software program for the quantitative assessment of subjective appetite-related sensations, using a visual scale and running on a handheld computing device. OKMO runs on inexpensive Palm devices (PalmOS 4), and was built using only free and open source software technologies. Over the years it has been used in five studies involving hundreds of subjects. The aims of the present case study are: a) to expose the considerations (device availability and cost, software licensing, localization) driving the technology decisions surrounding OKMO; b) to describe the medical studies that OKMO has enabled to date; and c) to describe the experience of the researchers and research subjects who used OKMO.

1 KEYWORDS

psychometric data collection, handheld computer, appetite-related sensations

2 INTRODUCTION

The measurement of appetite-related sensations (abbreviated ARS), such as hunger, fullness and desire to eat, has been of long-standing interest to the scientific community (medicine, nutrition, psychology). Efforts to unravel the obesity epidemic initially looked to ARS as surrogate measurements of food intake (Parker et al. 2004). In recent years the direct study of appetite, usually thought of as a psychometric variable (Hetherington 2002), and its relationship to physiological variables has also become popular.

ARS are typically measured on a visual analogue scale, which is an ungraded scale, with questions about the intensity of a particular sensation (e.g. ”How hungry are you?”). A set of such questions formed the basis for the Electronic Appetite Rating System (EARS), which ran on the Apple Newton palmtop computer (Stubbs et al. 2000). It was demonstrated that EARS could be used interchangeably with and pencil and paper questionnaires (Stratton et al. 1998).

In 2003 we undertook the design and implementation of OKMO, a visual appetite rating scale program using a direct translation of the questionnaire previously used in EARS to the Greek language, and a discrete, visual rating scale from 1 to 10. To date, five medical studies have been conducted that correlate ARS timeseries collected via OKMO with somatometric and blood serum measurement timeseries. In the present case study we discuss a) the technological design considerations (hardware cost and availability, licensing considerations, localization), b) medical research made possible by OKMO, and c) researcher and research subject experience related to using OKMO. In the discussion section we briefly touch on the impact of OKMO and related technologies, and how these technologies may look different depending on whether they are intended to function in a developed or developing world setting.

3 RESULTS

3.1 *Technological Considerations*

The design process of OKMO was affected by hardware availability and cost, the cost of software licensing and development, the desire to produce software

that could be improved and possibly shared in the future, and the fact that the software had to be localized for use in Greece.

When the design process began, in 2002, the handheld computer market was dominated by devices from Palm Inc, Sony and Handspring, all running Palm OS. The older, simpler and cheaper of those devices ran version 4.x of Palm OS, whereas the newer devices ran Palm OS 5, which had just been released. Palm OS 5 presented a distinct advantage over Palm OS 4.x: it supported Unicode, making localization in a non-Latin alphabet language like Greek much easier. However, Palm OS 5-based devices were more expensive, representing a higher initial investment in hardware and a higher risk for theft. In addition, Palm OS 5 devices were packed full of distracting and potentially intimidating software features, making them less suitable for use by the diverse patient population we expected to encounter. After careful consideration of these factors it was decided to use Palm OS 4.x-based hardware, at least at first.

The design choice to support Palm OS 4.x meant that Unicode was not an option for localization to the Greek alphabet. Some Greek fonts were commercially available for licensing, but we opted to design our own rudimentary Greek font and avoid the cost and complication associated with licensing fonts.

Because it was anticipated that the researchers commissioning the development of OKMO may want to continue to improve it, or may want to share it, it was decided that the source code of the software would be given to the researchers at the end of the development process.

In order to eliminate the cost of licensing software technologies, OKMO was based only on free or open source technologies. As a development environment we used PilRC, an open source Palm OS development environment for Linux. Cross-compilation was accomplished using the GNU C compiler, gcc. OKMO was packaged for installation to Palm hardware via a Windows desktop using Inno Setup, a free Delphi-based installation builder. The data gathered by OKMO was exported to a Windows desktop via a conduit written in Java, using the development libraries supplied by Palm Inc, in CSV (comma-separated variable) format.

3.2 *Medical Studies*

OKMO was used in the following studies, given in chronological order. The first study, whose purpose was to validate OKMO, involved young healthy individuals. Four studies involved adult patients, while one more involved pediatric patients.

3.2.1 *Water Intake*

The first study using OKMO involved 41 adult subjects (21/20 male/female). Anthropometric measurements (weight, height, body composition), and a self-reported estimate of physical activity were taken weekly. Instantaneous appetite related sensation (ARS) were measured once a week, in the morning, before and after the subjects drank 500 ml of water. Recall of ARS over the entire previous week was also recorded at the same time.

The study found that the instantaneous ARS of subjects with high Body Mass Index (BMI) were insensitive to water intake, while the the those of subjects with normal BMI changed as a result of water intake. ARS recall for the previous week, body composition and levels of physical activity were not found to be statistically significant predictors of ARS change due to water intake (Lampoudi et al. 2004).

3.2.2 *Menstruation*

The next study using OKMO was an extension of the first, involving 18 female subjects of child-bearing age. The methodology was the same as that of the water intake study, except that information about the subjects' menstrual cycle was also recorded. The subjects were assigned to one of two groups, depending on whether they were in the pre- (group A) or post-ovulation (group B) phase of their cycle.

The study found that groups A and B did not differ in their appetite scores, but group B did display higher satiety scores, which were further elevated by drinking water (Lampoudi et al. 2004).

3.2.3 *Intra-gastric Balloon and ghrelin*

The stomach secreted peptide ghrelin has been shown to be profoundly involved in human appetite regulation (Nakazato et al. 2001). The aim of this study was to explore this relationship in obese patients treated by intragastric balloon (IB). It was a prospective study of changes in ARS and ghrelin levels in 42 obese patients treated by IB. ARS scores, anthropometric measurements, food recall and blood serum ghrelin measurements were collected before IB placement and every month for the six months between placement and removal.

The study concluded that following IB insertion, ghrelin levels and ARS are suppressed in parallel. In cases of extreme weight loss, ARS and ghrelin levels are dissociated: ghrelin increases while ARS remain profoundly suppressed. Both ARS and ghrelin changes are correlated with the outcome. Since the long term benefits from IB placement are expected to derive from the modification of feeding behavior, the assessment of ARS could provide useful insight during the follow-up of these patients (Lampoudi et al. 2007a, Lampoudi et al. in preparation).

3.2.4 *Diabetes*

This was a prospective study of 40 (15/25 m/f) Type II diabetic patients. The purpose of the study was to investigate whether gastroparesis, a common symptom, was accompanied by changes in ARS and/or changes

in endogenous ghrelin levels. ARS scores, antrhopometric measurements, patient histories, blood panels and blood pressure measurements were taken.

85% of the patients in the study showed evidence of diabetic gastroparesis. A statistically significant correlation between gastroparesis and the time from the onset of diabetes was observed, but no such correlation was found between gastroparesis and ghrelin levels or ARS. It was concluded that, while the severity of gastroparesis increases with time elapsed from the onset of diabetes, basal ghrelin levels and the ARS of the patients remain unperturbed (Lampoudi et al. 2006).

3.2.5 *Juvenile arthritis, TNF-α and ghrelin*

This study aimed to examine the hypothesis that the adverse effect of TNF-α on appetite and weight gain is related to the suppression of ghrelin. 52 children (44 female) with juvenile arthritis (JIA), a disease with documented high levels of TNF-α, were studied. Anthropometric measurements, ARS and food recall measurements, blood serum ghrelin were measured. These were analysed in relation to disease activity and anti-TNF-α treatment.

The study concluded that conditions related to elevated TNF-α, such as systemic type of JIA and high disease activity, are associated with low levels of ghrelin. Anti-TNF treatment is associated with high ghrelin levels suggesting a possible suppression effect of TNF-α on ghrelin. However, no correlation was found between ARS and ghrelin levels (Lampoudi et al. 2007b).

3.2.6 *End-stage renal insufficiency*

This was a study of 59 (31/28 m/f) end-stage renal insufficiency patients on dialysis. ARS, anthropometric and ghrelin, creatinine and urea measurements were taken, and analysed in relation to the patients' nutritional status.

The study concluded that the nutritional status of the female patients was better than that of the male patients, independently of ghrelin level. Ghrelin levels were found elevated in a patient group in which they theoretically should not have been. This may indicate a deregulation of ghrelin receptor production and/or function in patients with end-stage renal insufficiency undergoing dialysis, especially males. Simple and multiple regression models using all the data collected were unable to account for 80% of the variability in ghrelin levels, indicating that other parameters, such as leptin and insulin levels, and co-existing conditions should be additionally measured in future prospective studies (Apostolou et al. 2008, Lampoudi et al. in preparation).

3.3 *Researcher and Research Subject Experience*

OKMO enabled researchers to collect timely, accurate and authoritative data about their research subjects within as well as outside the hospital setting. The recording of data by the patients themselves saved valuable researcher-research subject interaction time, which was used as an opportunity to further observe and engage the subjects regarding other aspects of their condition and behavior.

Theoretically, paper questionnaires and electronic data are both susceptible to loss. Nevertheless, in the six studies described here, it appears that not a single data point was lost during entry or retrieval. Collecting data via OKMO, as opposed to a traditional pen and paper questionnaire, was preferable for the researchers because it was more efficient and less error prone. Efficiency came from the fact that the data was already in a convenient electronic comma separated value (CSV) format when it was retrieved from the handheld devices, so the time spent converting data to such a format was freed for other tasks. The fact that there was no need for data transcription also removed the risk of introducing errors in the data. Analysis of partial or full datasets was straight-forward. It was performed with Microsoft's Excel spreadsheet program, and it could take place even while the studies were under-way (provided the researchers had physical access to the handheld devices).

Reasearch subjects were introduced to OKMO by the researchers in a training session. While research subjects initially seemed to prefer that someone else perform the data entry for them, they soon understood that using OKMO gave them a measure of independence and autonomy, and they quickly accepted. Most subjects had no difficulty using OKMO, once they were familiar with it. The only subjects who appeared to struggle were older subjects who were generally unfamiliar with electronics and could not become accustomed to OKMO.

Research subjects voiced a preference for carrying as few electronic gadgets as possible. Developing OKMO as a software-only solution, to be loaded onto subjects' own electronic devices, was not a realistic option in 2003. Most subjects did not own a handheld computer, and the cell phones prevalent in Greece at the time were neither powerful enough nor programmable in a straight-forward and portable manner.

4 DISCUSSION

The proliferation of user-owned, take-everywhere handheld computers, in the form of PDAs, smartphones and tablets, is a golden opportunity for the field of medicine. The collection and transmission of subjective (e.g. hunger, pain, stiffness), psychometric (e.g. anxiety, desire to eat), behavioral (e.g. compliance), and even elementary somatometric data (e.g. weight) has become trivial. This data stream feeds

medical research, as we have demonstrated in this case study. It is also an enablng technology for 21st century P4 ("Predictive, Preventive, Personalized and Participatory", a term coined by Leroy Hood of the Institute for Systems Biology) medicine.

Today devices with capabilities that far exceed those of the Palm handhelds on which OKMO was originally programmed are owned by a large majority of the public in rich, industrialized nations. If OKMO were to be designed today for use in Greece, it would be very different software, and it would likely run on many different user-owned handheld computer architectures. A networked data collection interface that would work on multiple types of smartphones is now trivial to build. Such an interface would address the wish of our research subjects to carry as few gadgets as possible. Data could be available to researchers or practicing physicians nearly instantly. Training research subjects or patients to use the software would be quicker and induce less anxiety, since the hardware would already be familiar. This is not to say that technological challenges do not exist in this domain. Concerns about confidentiality and data security are almost certainly the biggest obstacles to the wide adoption of such tools, which are otherwise extremely simple to build. But our experience suggests that these obstacles are worth tackling, as the use of these tools can be very productive.

Dismayingly, many of the technological decisions made for OKMO in 2003 in Greece would still be the best choices to make today, if OKMO were intended to be deployed in a developing world setting. Highly networked, user-owned electronic devices are only beginning to make their appearance in the developing world, and may not spread nearly as quickly as they did in the developed world due to a lack of infrastructure. If the hardware has to be part of the solution, then the choice of hardware must reflect a) the reality that a more valuable device has a higher chance of being stolen, and b) the fact that a more full-featured device is also more distracting. Open source software technologies are now even more mature and widespread than they were in 2003, and they are especially well-suited to the developing world, as they keep development costs low. The localization issues that we encountered are now nearly extinct, with Unicode support for most non-Latin alphabets being built into most mobile platforms.

It is our hope that sharing the list of questions we asked ourselves leading up to the design of OKMO, and the surprising success of using such a simple technological advance to enable numerous quantitative medical studies, will encourage others to embrace such projects, both in the rich and industrialized nations as well as in the developing world.

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