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**TEXT MESSAGING AS ADJUNCT TO COMMUNITY BASED WEIGHT  
MANAGEMENT PROGRAM**

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## BACKGROUND

Despite multidisciplinary initiatives to reverse ascending rates, the prevalence of overweight and obesity is still on the rise causing staggering related medical spending.<sup>1</sup> Numerous health co-morbidities are associated with obesity, including type II diabetes, hypertension, cardiovascular diseases and cancer.<sup>2</sup> The latest estimates from the National Health and Nutrition Examination Survey (NHANES) obtained in 2009 – 2010 revealed that 68% of adults in the United States are either overweight or obese making the quest for effective interventions to curb the obesity epidemic a public health priority.<sup>3</sup> Lifestyle interventions including physical activity, diet modifications, behavior therapy, and counseling appear to be the most successful interventions for short and long-term weight management and result in a greater weight loss as compared to interventions including diet and exercise alone.<sup>4-7</sup> Behavioral components such as self-monitoring, goal setting, problem solving, social support, and adherence to weight loss programs, have shown to be strong predictors of success in weight management.<sup>7-11</sup> Lifestyle interventions, however, are often limited by high costs, a decline in adherence to the intervention over time, location and time constraints to researchers and participants thus limiting accessibility to the general population.<sup>12,13</sup>

The ubiquitous spread of mobile phone Short Message System (SMS) appears to offer an effective alternative to face-to-face approach when delivering weight management interventions.<sup>14</sup> SMS has the advantage to instantly reach individuals and is accessed at own convenience and comfort, at a low cost when compared to other mediums such as phone calls.<sup>15</sup> Researchers have tested the utility of SMS across different preventive health behavior interventions. Findings suggest that SMS can be an efficient medium to provide patient education, appointment reminders, behavioral interventions, data acquisition and two-way

communications between individuals and healthcare providers.<sup>15-17</sup> In addition, tailored SMS have been shown to address individual needs and promote adoption of healthy behaviors in adults, through feedback, intervention initiation and interactivity between health providers and individuals.<sup>18, 19</sup>

Despite encouraging results, little research has explored the utility of SMS in adult weight management.<sup>20-23</sup> In most studies, SMS was used with other behavioral components, making it difficult to evaluate its true effect. Thus, the purpose of the study was to address the utility of SMS as a stand-alone intervention. The primary aim of the study was to assess the effects of tailored SMS on change in body weight. The secondary aim was to assess changes in behavioral outcomes in an experimental versus a control group of overweight and obese adults, participating in a structured community weight management program, since group interventions have been found to be superior to individual interventions in helping individuals reach their weight goals.<sup>24,25</sup> We hypothesized that tailored SMS would enhance weight loss in the intervention group, facilitate the adoption of healthy eating behaviors and increase time spent in physical activity per week. In addition, it will improve exercise and nutrition self-efficacy, attitude toward technology and social support. We anticipated that this study would help shed the light on the usefulness of SMS among participants and identify areas of intervention that need improvement.

To synchronize the different concepts and variables applicable to promoting behavioral change in overweight and obese population, the revised Health Promotion Model served as a conceptual framework to guide the study.<sup>26</sup>

## METHODS

### Design, sample and settings

A pilot quasi-experimental study was conducted over 12 weeks and was approved by the Virginia Commonwealth University Institutional Review Board. Participants consented and were recruited from a “Weight Watchers at work” weight management program. Weight Watchers (WW) was deemed to be the only commercial program with a proven efficacy through a multisite randomized controlled trial, to produce a 5% weight loss of initial body weight at 1 year and maintain a weight loss of 3.2% at 2 years.<sup>27-28</sup> Participants were assigned to an intervention or control group based on their WW meeting location in an effort to conserve the group cohesiveness. Assessment was conducted at baseline and at 12 weeks. The primary health outcome was change in body weight. Secondary behavior outcomes included: Eating behaviors, exercise and nutrition self-efficacy, physical activity, social support, attitude toward technology and adherence to the intervention.

The researcher introduced verbally the intervention and interested participants were provided written informed consent to read, sign and return prior to participation. Participants either completed the questionnaires on site or returned them on the following meeting. All participants received monetary compensation (\$10.00) upon completion of baseline questionnaires and were entered into a drawing to win one session with a personal trainer upon completion of the post-intervention questionnaire.

A total of 35 participants were recruited from “Weight Watchers at work” group meetings on both campuses of Virginia Commonwealth University, during three consecutive weekly meetings, in June 2012 (Figure 1). Participants were eligible if they were healthy overweight or obese adults (BMI range of 25 – 40 kg/m<sup>2</sup>), 18 years and older, own a mobile

phone with enabled text messaging service and enrolled in the “Weight Watchers at work” program. Exclusion criteria included pregnancy, a BMI  $\leq 25$  or  $\geq 40$  kg/m<sup>2</sup> and non-possession of mobile phones.

### **Intervention**

All participants attended WW at-work weekly meetings. An independent online health promotion company (<http://www.infieldhealth.com>), located in Washington, D.C, initiated and implemented the intervention by sending biweekly SMS to the intervention group and storing participants’ responses in its database. Each message included 159 characters or less, suggested the application of a healthy behavior challenge and ended by a “reply yes or no”. Participants were expected to text back “yes” upon completion of the requested behavior or “no” if they did not do it. They were also informed that they may text “Stop” at any time they wished to opt out of the study. The content of messages was tailored to address the overall group’s perceived health and behavior barriers that hindered weight loss efforts as listed by participants on the baseline questionnaire. Identified barriers were primarily related to unhealthy eating behaviors, lack of time, inconsistency in exercise routine and strong emotions altering healthy eating choices. Accordingly, during the 12 week intervention, each SMS varied in content suggesting ways to adopt a healthy behavior and overcome a perceived barrier. For instance, participants referred to having poor food choices when hungry so the suggested health challenge was to prepare food ahead of time or have handy a healthy snack. The control group did not receive any SMS.

### **Instruments and outcome measures**

The assessment was done at baseline and at the end of the intervention at 12 weeks. Data was collected in June and September of 2012. The outcome measures were body weight, eating

behaviors, exercise and nutrition self-efficacy, social support, physical activity and attitude toward technology. Body weight was measured by a trained WW staff, using a digital scale (Tanita C-400 ®, Arlington Heights, Illinois) and recorded on participants' weight charts. Participants and researchers were not blinded to body weight. Height was self-reported. Eating behaviors were measured by the Weight Related Eating Questionnaire (WREQ) which measures cognitive, emotional eating and dietary restraints in relation to body weight.<sup>29</sup> The Physical Activity and Nutrition Self-efficacy (PANSE) scale was used to measure exercise and nutrition self-efficacy among participants.<sup>30</sup> Attitude toward technology was measured using questions adapted from the Technology Acceptance Model which measures the perceived ease of use as well as the usefulness of the technology.<sup>31</sup> Social support was measured by using questions adapted from the Interpersonal Support Evaluation List (ISEL), which measures the perceived availability of social support resources.<sup>32</sup> Physical activity was measured by the International Physical Activity Questionnaire (IPAQ) Short form (*SF*) and reported by the MET-minutes per week, computed by multiplying the MET score of an activity by the minutes performed.<sup>33</sup> Adherence to the intervention was measured by the percentage of responses to prompting SMS requests. At the end of the intervention, participants evaluated the usefulness of SMS.

### **Statistical Analysis**

Data analysis was performed in October 2012 with JMP Pro for windows, version 10, Cary, North Carolina. Based on a power analysis, with 80% power and an alpha of 0.05, 30 subjects per group were needed to detect changes in the outcome variables pre to post-intervention. In anticipation of lower sample size than the one needed to detect the difference, a one sided p-value was adopted stating that the intervention group would have greater weight loss and positive behavioral change as compared to the control group. Statistical analysis was



performed excluding participants with missing follow-up data on the outcome measures. Summary statistics were used to describe the sample including means, standard deviations, and ranges for the continuous variables, and counts with frequencies for the categorical variables. An analysis of variance ANOVA was used to examine any differences in baseline characteristics between groups for the continuous variables and Fisher's exact test for the categorical variables. A mixed model repeated measures ANOVA was used to detect any significant changes in outcome variables from baseline to 12 weeks, accounting for within participant differences (time) and possible interaction effects (group x time). For repeated measures ANOVA, the eta squared ( $\eta^2$ ) was used to calculate the effect size.<sup>34</sup>

## RESULTS

### Participants

Thirty five patients signed the consent form. Of the 35 participants, 7 were excluded because they did not fulfill the inclusion criteria and 2 were lost to follow up. Data from 26 participants was included in the final analysis (13 were in the intervention group and 13 in the control group). There was no difference between groups at baseline in socio-demographic characteristics, anthropometric or behavioral measures. The mean age for the intervention group was 46.6 years versus 42.5 years for the control group. The mean BMI for the intervention group was 33 kg/m<sup>2</sup> versus 32.8 kg/m<sup>2</sup> for the control group. Baseline characteristics of the two groups are presented in Table 1.

### Weight change as a health outcome

Mean body weights were compared between the two groups at 12 weeks and within group pre- to post-intervention (Table 2). The mixed model repeated measures ANOVA indicated that there was a significant weight loss at 12 weeks ( $F_{(1, 24)} = 3.01, p = 0.047$ ). The

Least Squares Means contrast indicated a significant weight loss in the intervention group [5.96 lb.; 95% CI = 2.14 – 9.79] as compared to the control group [1.41 lb.; 95% CI = - 2.41 – 5.24] (Figure 2). The effect of SMS on weight loss was 0.02 which is considered small according to the Cohen classification.<sup>35</sup>

### **Behavioral outcomes**

The change in eating behaviors, exercise and nutrition self-efficacy, social support, physical activity and attitude toward technology were also compared between the two groups at 12 weeks, and within group, using a mixed model repeated measures ANOVA (Table 2). At 12 weeks, there was no significant difference in eating behaviors between groups ( $F_{(1, 24)} = 2.34, p = 0.06$ ). However, an improvement was detected in the eating behaviors scores in the intervention and no change the control group. Similarly, at 12 weeks, the intervention scored higher than the control group on the exercise and nutrition self-efficacy but the difference between groups was not statistically significant ( $F_{(1, 24)} = 2.46, p = 0.06$ ). As for social support, there was no significant difference between groups, ( $F_{(1, 24)} = 0.0016, p = 0.48$ ) nor a change from baseline scores in either group.

Physical activity was assessed by calculating the total MET-minutes per week spent in vigorous and moderate physical activity or walking, in addition to total weekly hours spent in sitting. At 12 weeks, there was an increase in the total MET-minutes per week spent in physical activities in the intervention group but not in the control group, but the difference between groups was not significant ( $F_{(1, 8.17)} = 0.22, p = 0.64$ ). At 12 weeks, there was no significant difference between groups in the weekly hours of sitting ( $F_{(1, 24)} = 0.71, p = 0.20$ ), as well as any change from baseline scores in both groups. Furthermore, there was no significant difference

between groups concerning attitude toward technology at 12 weeks ( $F_{(1, 24)} = 0.04$ ,  $p = 0.41$ ) and no change from baseline scores in both groups.

### **Adherence to the intervention**

Adherence to the intervention was measured by calculating the total number of bi-weekly participants' responses to health challenges over 12 weeks. Participants were considered adherent when they replied by "yes" or "no" to a health challenge and non-adherent when they did not reply at all. At the beginning of the intervention, the participants' response rate to SMS requests was 66%. This percentage declined to 52% at the end of the intervention.

### **Participants' feedback**

At 12 weeks, participants in the intervention group answered five questions posed by the researchers asking if SMS were motivational, the timing and frequency were acceptable, the ability to complete the health challenges and if SMS helped in making good choices related to eating and exercise. Responses were categorized into: "not at all", "somewhat" and "very much". The content analysis of participants' responses was mainly related to the timing of SMS. One participant wrote "SMS would come mid-day when I was too busy to deal with". Another participant commented "SMS always come when I'm driving and I can't do anything about it". Some participants suggested allowing more time to complete the health challenges before asking if they completed it or not. In general, 72% of participants found SMS to be "somewhat" to "very motivational". All participants agreed that the biweekly frequency of SMS was "somewhat" to "very much" acceptable. A total of 73% found that the timing of SMS was "somewhat" to "very much" adequate. A total of 80% of participants were able to complete the requested health challenges and 79% agreed that SMS were "somewhat" to "very helpful" in making healthy choices related to eating and exercise.

## DISCUSSION

Findings from this study suggest that SMS mobile technology can be as effective a way to disseminate behavioral weight loss interventions as face-to-face behavioral interventions. The strength of this study resides in the SMS being the primary intervention, which differs from other weight loss studies that combined SMS with other behavioral components making it difficult to assess its true effect.<sup>21-23</sup> Despite a small sample size, participants in the intervention group were able to lose 4.5 lb. more than the control group. This weight loss is consistent if not greater than results from previous studies using SMS intervention for weight management.<sup>20-22</sup> Participants were able to achieve a total of 3% weight loss from their initial body weight, a percentage that compares favorably with previous research of 12 weeks duration.<sup>22, 36-38</sup> In addition, the retention rate was 96.4%, a high percentage when compared to similar studies<sup>22, 38, 39</sup> with respective attrition rates of (47%, 84.8%, 87%).

At 12 weeks, the intervention group scored higher on exercise and nutrition self-efficacy and eating behaviors as compared to the control group and had an increase from baseline scores, demonstrating a positive behavioral trend but did not have sufficient statistical power to achieve significance ( $p = 0.06$ ). Similarly, the intervention group had an increase in the total MET-minutes per week spent in physical activity, as compared to the control group, but this difference did not reach statistical significance as well, due to a low sample size. Both groups had high scores in attitude toward technology at baseline and at 12 weeks with no significant difference between groups. This may be related to the fact that all participants were owners of mobile phones and were familiar with various technology features.

In the current study, social support scores did not improve from baseline in either group. Although, the intervention group received encouragement statements by SMS upon completion

of behavior challenges, all participants were receiving support in their weekly WW meetings. This might explain the reason for lack of change in social support scores since WW meetings can provide substantial support for both groups.<sup>40</sup> In future studies, perceived social support can be further enhanced by offering participants online access to educational websites, virtual chat rooms or more interaction between participants and researchers.<sup>41, 42</sup>

This pilot study has several limitations. The percentage of male participants was minimal, an aspect common in weight loss studies. Participants were not randomized but were selected depending on their meeting location to preserve the group cohesiveness. All participants were enrolled in a weight loss program and motivated to lose weight, thus limiting generalizability of findings to the general population who may not be motivated to lose weight or enrolled in a weight management program. The sample size was less than what was needed to have power to detect significant differences. This may have prevented some outcome measures such as exercise and nutrition self-efficacy, eating behavior and physical activity from reaching statistical significance. Future studies with a larger sample size are needed to evaluate the true effect of SMS on behavioral changes. Exercise frequency, type and duration were based on participants' self-reports, which can be under or overestimated. Future studies should combine self-reports with an objective measurement such as use of accelerometers for more accuracy.<sup>43</sup> The current SMS intervention was not individually tailored, but rather addressed the overall group's perceived barriers. Research suggests that individually tailored messages can enhance weight loss and increase adherence to the intervention.<sup>44-45</sup> The lack of individualized SMS may as well explain the low rate of adherence among participants. The intervention was of short term and limited to 12 weeks. Long-term follow-up trials with adequate sample size are needed to assess

the efficacy of SMS in maintaining long term behavioral changes and further explore innovative ways to optimize and increase the adherence to the intervention.

## **CONCLUSION AND SUMMARY**

This pilot study was conducted to assess the effects of tailored SMS on body weight and behavioral changes in overweight and obese adults enrolled in a community weight management program. The findings support existing knowledge that tailored SMS may enhance weight loss among overweight and obese adults and may increase exercise and nutrition self-efficacy, healthy eating behaviors along with total time spent in physical activities. Companies, hospitals and clinicians looking for efficient and innovative platforms to implement weight management interventions may consider using SMS to improve weight loss in overweight and obese adults.

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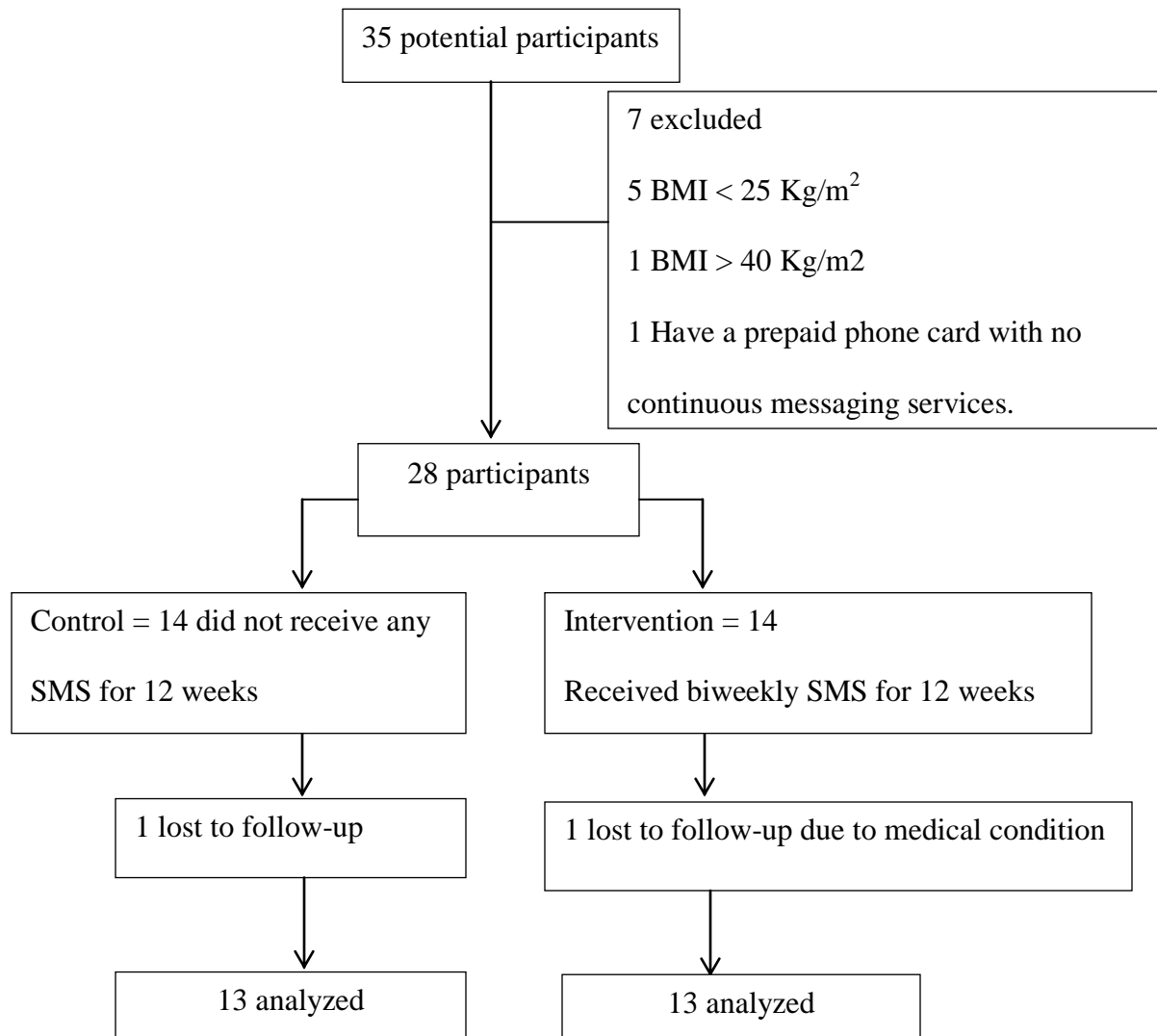
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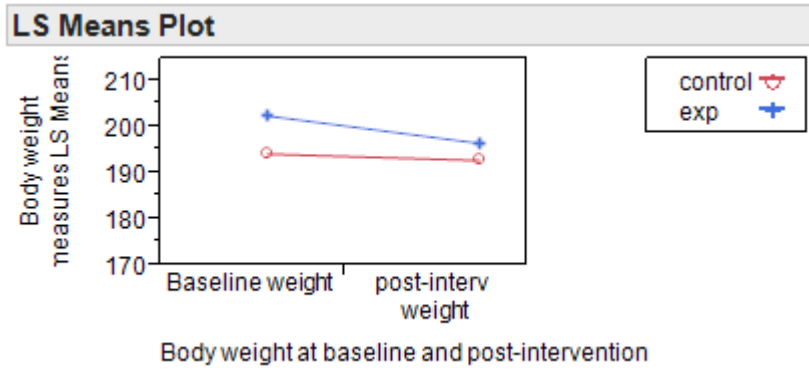
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**Figure 1.** Study participants flowchart

**Figure 2. Least Squares Mean Plot for body weight**



**Table 1. Baseline characteristics of participants by group**

Participants Characteristics	Control (n)	Intervention (n)	p-value
Age: years (M ± SD)	42.5 ± 12.3	46.6 ± 11.8	0.37
Gender: Female (%)	13 (93%)	13 (93%)	1.0
Race White (%)	10 (72%)	8 (57%)	0.54
Technology experience (%)	14 (29%)	14.4 (30%)	0.78
Text messaging/week: 1-20	7 (50%)	5 (36%)	0.5
Education: no college degree	3 (21%)	4 (29%)	0.34
Income: 25.000-50.000	6 (43%)	4 (29%)	0.76
Marital status: married	7 (50%)	8 (57%)	0.82
Body Mass Index kg/m <sup>2</sup>	32.8 ± 3.5	33 ± 4.8	0.92
Weight in pounds (M ± SD)	193.4 ± 27.6	206.3 ± 35.6	0.29
Eating behaviors (%)	44.5 (55.6%)	43.4 (54.2 %)	0.72
PANSE (%)	36.2 (82.2%)	33.9 (77%)	0.27
Social support (%)	54.4 (85%)	54.5 (85.1%)	0.97
Technology attitude (%)	20.3 (81.2%)	19.4 (77.6%)	0.65
Total Physical activity, MET-minutes/week (M ± SE)	2563.66 ± 916.35	2414.32 ± 561.15	0.89
Sitting hours/day (M ± SD)	8.00 ± 2.82	6.45 ± 2.69	0.17
<b>Total number</b>	<b>14</b>	<b>14</b>	

Abbreviations: n: number; M: mean; PANSE: Physical Activity and Nutrition Self-Efficacy; SD: Standard Deviation; SE: Standard Error.



**Table 2. Summary of Findings**

<b>Variables</b>	<b>LS Mean</b>	<b>Standard Error</b>	<b>95% Confidence Interval</b>
Control, baseline weight in lb.	194.18	8.49	176.69 – 211.68
Control, post intervention weight in lb.	192.77	8.49	175.28 – 210.26
Experimental baseline weight in lb.	202.48	8.49	184.99 – 219.97
Experimental post intervention weight in lb.	196.51	8.49	179.02 – 214
Control, baseline PANSE	35.84	1.37	33.04 – 38.64
Control post intervention PANSE	35.84	1.37	33.04 – 38.64
Experimental baseline PANSE	33.84	1.37	31.04 – 36.64
Experimental post intervention PANSE	36.69	1.37	33.89 – 39.48
Control, baseline eating behaviors	45.15	2.39	40.31 – 49.99
Control post intervention eating behaviors	44.30	2.39	39.46 – 49.14
Experimental baseline eating behaviors	42.84	2.39	38 – 47.68
Experimental post intervention eating behaviors	47.69	2.39	42.85 – 52.53
Control, baseline social support	54.15	1.72	50.64 – 57.66
Control post intervention social support	54	1.72	50.48 – 57.51
Experimental baseline social support	54.38	1.72	50.87 – 57.89
Experimental post intervention social support	54.3	1.72	50.79 – 57.81
Control, baseline technology attitude	20.07	1.32	17.37 – 22.77
Control post intervention technology attitude	20.38	1.32	17.68 – 23.08
Experimental baseline technology attitude	19.07	1.32	16.37 – 21.77
Exp. Post intervention technology attitude	19.69	1.32	16.99 – 22.39
Control, baseline total PA MET-minutes/week	2482.7	957.82	441.15 – 4524.3
Control post-intervention total PA MET-min/week	2410.6	957.82	368.98 – 4452.2
Experimental baseline total PA MET-minutes/week	2401.0	572.28	1180.8 – 3621.2
Exp. post intervention total PA MET-minutes/week	3093.3	767.32	1457.6 – 4729
Control, baseline total hours of sitting/day	8.00	0.71	6.36 – 9.32
Control post intervention total hours of sitting/day	8.30	0.71	7.02 – 9.97
Experimental baseline total hours of sitting/day	6.30	0.83	4.61 – 8.04
Experimental post intervention total hours of sitting/day	6.35	0.81	4.66 – 8.03

Abbreviations: Exp: Experimental; PA: Physical Activity; PANSE: Physical Activity and Nutrition Self Efficacy.

**MOBILE TECHNOLOGY STRATEGIES AND WEIGHT MANAGEMENT: A  
SYSTEMATIC REVIEW**

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### Abstract

This systematic review was conducted to determine the utility of mobile technology as an adjunct to weight management interventions in overweight and obese adult population. Studies using mobile technology to administer weight loss interventions in healthy overweight and obese adults were eligible. Studies including pediatric population or participants with underlying disease were excluded. Study characteristics and results were gathered and synthesized. The search identified 518 citations from PubMed, PsychInfo, CINAHL, Web of Knowledge, and gray literature. A total of 14 articles met the inclusion criteria and were conducted between the year 2007 and 2011. The main outcome measured in the studies was the change in body weight of participants. The secondary outcome was to report the components of mobile technology that were most frequently used and their correlation with change in body weight. A total of 7 studies reported significant findings; the remaining 7 studies did not find significant difference in body weight between groups. The duration of interventions varied in length from 5 weeks to 12 months. The majority of studies reported participants' satisfaction with mobile technology. Text messaging, followed by mobile applications were the most used components of mobile technology. In addition, interventions using SMS to administer weight management interventions were more likely to achieve significant results. More rigorous interventions are needed to test and compare different components of mobile technology and their utility in weight management interventions.

**Key words:** Mobile technology, weight loss, behavioral therapy, health promotion methods.

## INTRODUCTION

Effective interventions to curb the high prevalence of obesity are still a public health priority. Despite great multidisciplinary initiatives and targeted interventions, obesity rate is still on the rise. The latest estimates from the National Health and Nutrition Examination Survey (NHANES) obtained in 2009 – 2010, revealed that 68% of adults in the United States are either overweight or obese. Obesity prevalence was 35.5% among men, and 35.8% among women, although prevalence rates vary largely between population groups (Flegal et al., 2012). Obesity is associated with increased risk of health co-morbidities including type II diabetes, hypertension, cardiovascular diseases and cancer (Lawrence et al., 2004) and presents a great public health concern associated with staggering related medical spending (Finkelstein et al., 2009).

Although different modalities exist to manage obesity, lifestyle interventions have been demonstrated to be successful for both short and long-term weight loss in overweight and obese individuals (Galani and Schneider, 2007; Brown et al., 2009; Goodpaster et al., 2010). Research has shown that even a small reduction of 5% – 10% in initial body weight can reduce the obesity related comorbidities (Blackburn G., 1995; Pasanisi et al., 2001; Ross et al., 2009). Lifestyle interventions often combine diet, exercise and behavioral treatment and may include counseling individuals to adopt and maintain healthy behaviors (WHO, 2004; Wadden T., 2000). In a systematic review of 36 behavioral and cognitive-behavioral interventions, the evidence implied that a combination of behavioral treatment with diet and exercise resulted in a greater weight loss than diet and exercise alone (Shaw et al., 2005). Recently, the ubiquitous presence of cellular phones and mobile technology offers a great promise in facilitating the administration of obesity interventions as well as adherence to behavioral weight management strategies (Tufano and

Karras, 2005). According to the International Association for the Wireless Telecommunications Industry, as of June 2011, the United States has an estimated 322.9 million wireless subscribers (CTIA, 2011). The new generation of “smartphones” facilitates an accurate self-monitoring tool for diet and exercise and generates instant feedback on individuals’ lifestyle, weight goal and overall progress.

Despite the great potential for dissemination of overweight and obesity tailored interventions at the population level, there is still no clear understanding of the underlying mechanisms and effects of different mobile technology components used in health promotion interventions (Patrick et al., 2009). To our knowledge, there has been no systematic review evaluating the benefits of mobile technology in interventions focused on weight management in overweight and obese adults. Therefore, the specific aim of the present review was to systematically assess the effectiveness of mobile technology in the application of lifestyle interventions for short and long-term weight loss in healthy adults with body weight change as the primary outcome measure. The secondary aim was to explore which components of mobile technology were used most frequently and the relationship to change in body weight.

## **METHODS**

The current systematic review adopted a protocol suggested by the updated method for systematic reviews in the Cochrane Collaboration Back Review Group (Furlan et al., 2009). For the purpose of this review, weight management was defined as interventions focusing on overweight and obesity prevention and promoting reduction in body weight. Mobile technology has been defined as handheld devices that are constantly carried by individuals all day (Riley et al., 2011) this definition includes cellular phones, personal digital assistants (PDAs), iPods or other handheld mobile devices that allow healthcare providers to interact with individuals.

Laptops, netbooks, and iPads were excluded from this definition since they are not carried by individuals throughout the day.

### **Inclusion and exclusion criteria**

Studies were included if they were: (1) published in English, (2) focused on the adult population, 18 years and older who were evaluated as healthy overweight or obese (3) used mobile technology to deliver a weight loss intervention, and (4) used change in body weight as an outcome measure. There was no limitation set on date of publication since the effect of mobile technology on health was considered an emerging field of research. Articles were excluded if (1) they were review or editorial articles and did not contain interventions for weight loss, (2) did not have change in body weight as an outcome measure, (3) used other forms of technology such as Internet or e-mails or used other forms of portable mobile technology (armbands), (4) Studies assessing the utility of mobile technology to enhance physical activity alone (5) studies including subjects with underlying disease.

### **Types of interventions**

The current review included all types of interventions that compared the usage of technology for weight management such as short messaging system service (SMS) versus weight loss printed materials, mobile applications or podcasts for self-monitoring and individualized weight loss plan, and PDAs with or without feedback, versus standard behavioral treatment for weight loss.

### **Outcome measures**

The primary outcome measure was the change in total body weight from baseline, either recorded by the researchers or self-reported in pounds or kilograms or as a body mass index (BMI). Waist circumference and waist to hip ratio were not included in the outcome

measurement since they were not constantly reported in the selected studies. The secondary outcome was to report the components of mobile technology that were most frequently used and their correlation with change in body weight.

### **Search strategy**

The following electronic databases were searched: PubMed, PsychInfo, CINAHL, Web of Knowledge, databases of ongoing trials, including the Clinical Trials registry of the U.S. National Institute of Health, and the Cochrane Central Register of Controlled Trials (CENTRAL). The reference lists of relevant articles were manually searched to identify additional studies, and a search in grey literature was also performed. The search was based on these keywords: weight loss, obesity therapy, body weights and measures, diet records, behavioral therapy, cellular phone, computers handheld, smartphone, mobile technology, mobile health and mobile application. The search in PubMed included the following Mesh terms: weight management OR weight loss OR diet reducing OR Body weights and measures OR diet records OR electronic diary AND mobile application OR personal digital assistant OR mobile health OR mobile technology OR cellular phone OR mobile device OR handheld computers OR mobile phone OR Monitoring, Ambulatory/methods AND behavior methods OR behavior therapy OR cognitive therapy OR cognitive methods OR health promotion methods.

During the electronic search of databases, additional keywords of relevance were also attempted. When an abstract could not provide sufficient information, the entire article was retrieved for further assessment. Full articles of relevant studies were obtained for assessment against inclusion criteria. Two researchers (CB and JS) independently accessed the retrieved articles for eligibility based on inclusion criteria and agreed upon the final articles to be included in the review.

### **Data synthesis**

The studies included in the review were summarized in Table 1, which provides characteristics of participants, types of interventions, duration of the study, follow-up time, outcome measures and results. A synthesis from the studies could not be pooled due to the large heterogeneity among studies regarding methodology, intervention, outcomes and the type of mobile technology used. A qualitative analysis comparing the selected studies was provided.

### **Studies retrieved**

The search strategy retrieved a total of 518 articles. After screening the articles for inclusion and exclusion criteria, a total of 12 articles met inclusion criteria. When reference lists of articles were screened, no additional articles were found. A search of grey literature yielded two dissertation studies related to mobile technology use and weight loss, resulting in a total of 14 studies included in the systematic review.

## **FINDINGS**

### **Description of included studies**

The selected studies were conducted between 2007 and 2011. A total of 7 of the 14 studies were randomized clinical trials (RCTs). A total of 4 studies used a control experimental design without the randomization, and 3 studies used within subject comparison design. A total of 7 studies including 3 RCTs reported significant findings. The remaining 7 studies including 3 RCTs did not find significant difference in body weight between groups. The duration of interventions varied in length from 5 weeks to 12 months.

### **Sample and setting**

All studies included adults with sample sizes ranging from 25 to 463 participants. A total of 1,547 participants were evaluated in the 14 selected studies. We excluded the total number of



participants in one study (n= 36), which did not report the gender (Lee W. et al., 2010) and calculated out of the remaining number (n= 1511) the percentage of female participants (76%) in overall studies. All studies included both genders except for one which included only women (Lee C. et al., 2011). Participants ranged from 18 to 70 years old. The BMI of participants was between 22 –40 kg/m<sup>2</sup>. Recruitment was primarily from communities (Joo and Kim, 2007; Burke et al., 2010) using newspaper advertisements, flyers (Yon et al., 2007; Patrick et al., 2009; Haapala et al., 2009; McGraa, K., 2010), and e-mails (McGrievy et al., 2009; 2011), at institutional sites (Morak et al., 2008; McDoniel et al., 2009; Lee W. et al., 2010; Cunningham B., 2011) or public health centers (Lee C. et al., 2011). One study did not state the recruitment strategy for its participants (Mattila et al., 2010). A total of 8 studies were conducted in the United States, one study in Austria (Morak et al., 2008), 3 in Korea (Lee W. et al., 2010; Lee, C. et al., 2010; Joo and Kim, 2007) and 2 studies in Finland (Haapala et al., 2009; Mattila et al., 2010).

### **Content of the interventions**

A wide variation existed in nutritional recommendations provided to participants and varied between increasing the consumption of fruits and vegetables, along with general advices on diet and exercise (McGrievy et al., 2009; 2011); decreasing food portion, heavy meals and increasing light snacks (Mattilla et al., 2010); cutting an average of 500 calories per day (Joo and Kim, 2007; Patrick et al., 2009) or even 1000 kcal per day (Yon et al., 2007). Other studies provided tailored nutritional and exercise plan to individuals (Morak et al., 2008; Burke et al., 2010; McGraa., 2010; McDoniel et al., 2009; Lee W. et al., 2010; Haapala et al., 2009; Lee C. et al., 2010; Cunningham B., 2011).

### **Technology components and correlation with change in body weight**

The mobile technology components used to deliver behavioral weight loss interventions differed widely between studies.

#### *Short Messaging System*

A total of five studies relied on SMS to deliver behavioral weight loss interventions with the rate of sent messages varying between weekly to 2-5 times daily. Out of the five studies, two relied on SMS as a stand-alone intervention.

Haapala et al. (2009) randomized 125 participants to an experimental group using a mobile phone application Weight Balance® and a control group who did not receive any intervention. Participants in the experimental group were encouraged to report their daily weight via SMS and received text messages tailored to individual responses. At 12 months, the experimental group had significant weight loss as compared to the control group ( $p = 0.006$ ).

McGraa K. (2010) assigned 65 subjects to an experimental group to explore the effect of persuasive motivational text messaging on adherence to diet and exercise and a control group who did not receive any intervention. All participants were asked to record their food intake, exercise, stress, motivation and weekly weight. Motivational SMS were sent to the experimental group three times daily. After five weeks, there was no significant difference in BMI between both groups ( $p=0.89$ ).

The following three studies included additional components to SMS.

Patrick et al. (2009) randomized 78 participants into an experimental group receiving personalized SMS and Multimedia Message Service (MMS) 2 to 5 times daily, in addition to educational printed materials and a brief monthly phone call from a counselor. The control group received monthly printed materials only. The tailoring in the SMS was limited to the time

preference and the frequency of message delivery. The topic of messages was changed weekly and included behavioral, diet and physical activity components. At four months, there was a significant difference in bodyweight between the intervention and control group ( $p = 0.02$ ).

Lee C. et al. (2010) used a quasi-experimental intervention to deliver a self-management intervention program including healthy diet and exercise relying on biweekly SMS and monthly phone counseling. The control group received a structured exercise program consisting of a three 1 hour walking class per week. At 12 weeks, BMI decreased in both groups but there was no significant difference between groups. The attrition rate in both groups was higher than 50%.

Joo and Kim (2007) used within subjects comparison design to assess the utility of SMS as a medium to deliver an obesity behavioral treatment. A total of 463 participants received a weekly behavioral SMS along with a weekly brochure on exercise and diet sent by mail. At 12 weeks, participants exhibited a significant reduction in body weight (1.5 kg) and BMI (0.06 kg/m<sup>2</sup>).

#### *Personal Digital Assistant*

Yon et al. (2007) assigned participants to an experimental group to use a PDA for self-monitoring diet and exercise and compared them to a control group from previous study that used traditional diaries. At six months there was no significant difference in BMI between groups ( $p = 0.68$ ).

Burke et al. (2010) evaluated PDA technology in an intervention consisting of three groups: one group used paper dairies, the second used PDAs, and the third used PDAs and received a daily feedback. All participants received standard behavioral treatment for obesity. At six months there was no significant difference in body weight among groups.

### *Mobile application*

Three studies used mobile phone applications to deliver a weight loss intervention.

Mattila et al. (2010) used a mobile phone diary application "Wellness Diary" for self-observation of daily weight and exercising using a pedometer in 27 participants for 12 weeks. Participants were asked to send their data to researchers weekly. At the end of the intervention, participants had a significant weight loss of an average 2.6 kg.

Lee W. et al. (2010) used a case control design to test the effectiveness of a mobile phone application "Smart Diet" and a diet game on weight control. The control group did not receive any intervention. The assessment at six weeks revealed a significant decrease in weight (1.9 Kg), fat mass and BMI (0.8 kg/m<sup>2</sup>) in the intervention as compared to the control group ( $p < 0.05$ ).

Cunningham B. (2010) assigned 47 participants to three groups: one group using a mobile application "lose it" to self-monitor diet and exercise, a second group using the "memo" function of mobile phones to record dietary intake and a third group using paper diaries for self-monitoring. After eight weeks, all groups lost weight but there was no significant difference in weight loss between groups.

### *Podcasts, social networking and mobile application*

McGrievy et al. (2009) used Podcasts to deliver behavioral intervention based on social cognitive theory. The control group received a popular weight loss podcast along with printed materials. The experimental group received behavioral weight loss podcasts. At 12 weeks, there was a greater weight loss in the experimental versus the control group ( $p < 0.001$ ).

In a later study, McGrievy et al. (2011) randomized 96 participants into two groups: an experimental group receiving Podcasts, along with downloadable mobile application to self-monitor diet and exercise (FatSecret.com), in addition to a mobile application for social

networking (Twitter) and a control group receiving Podcasts only. At six months, there was no significant difference in weight loss between the two groups ( $p = 0.88$ ). In addition the two groups did not differ in regard to diet monitoring and social support.

#### *Mobile phones as a platform for web access*

Morak et al. (2008) assessed the utility of mobile phones for participants as a platform to access a web-based therapy management system, communicates change in body weight information with investigators and receive reminders to enter their data. A total of 25 subjects were compared at baseline and after 70 days. At the end of the intervention, participants had a significant loss of 2.4 kg of body weight ( $p < 0.001$ ).

McDoniel et al. (2009) randomized participants into an experimental group to use a nutritional program which calculates nutritional and exercise requirement based on resting metabolic rate captured by a computer hand-held device (MedGem®), versus a control group receiving usual care. At 12 weeks, there was no significant difference in body weight between the experimental and control group ( $p = 0.19$ ).

### **MAJOR CORELATES WITH WEIGHT LOSS**

#### **Self-monitoring**

The majority of studies found that the frequency of dietary self-monitoring was strongly associated with weight loss, (Yon et al., 2007; Mc Doniel et al., 2009; Mattila et al., 2010) and stressed the importance of continuous self-monitoring in order to achieve the greatest weight loss. and advised participants to report daily weight.

Mattila et al. (2010) advised participants to weigh daily, to have relapse prevention due to a normal weight fluctuation and the importance to account for the fact that weight is usually

higher during weekends than week days. Awareness of weight fluctuation may help individuals to create a compensation system to adjust for imbalance in energy intake.

### **Adherence**

The majority of the studies, who measured adherence, reported a positive correlation between higher rates of adherence to usage of mobile technology and weight loss (Morak et al., 2008; Haapala et al., 2009; Patrick et al., 2009; Burke et al., 2010; Cunningham B., 2010). The adherence to self-monitoring was in general higher in experimental groups using mobile technology as compared to control groups (Burke et al., 2010). Remarkably, adherence reached its highest at the beginning, than started to drop toward the end of the intervention (Patrick et al., 2009; Burke et al., 2010). Haapala et al. (2009) reported that adherence to mobile phone usage dropped from 8 times per week to 3-4 times per week by one year. Similarly, Burke et al. (2010) noticed that adherence to self-monitoring started to decline by the third week of the intervention.

### **Feedback**

One of the important features reported in the usage of mobile technology was the capacity of providing instant feedback to participants related to their energy balance. Seven studies reported the utility of feedback in weight loss interventions. Participants in Haapala et al. (2009) study reported that immediate feedback was one of the most useful features in the intervention. Data entry and messages sent by participants led to the generation of automatic tailored response text message encouraging participants to adopt healthy eating and exercise behaviors. In Burke et al. (2010) study, 63% of the participants who used the PDA and received feedback, achieved  $\geq 5\%$  total weight loss as compared to the PDA and paper group. Mattila et al. (2010) reported that daily tailored feedback greatly enhanced weight loss and displayed causal relationship between behavior and weight loss. Patrick et al. (2009) used participants' response

to SMS to create positive reinforcement for healthy behaviors with responses being tailored to the frequencies of messages received from participants. Yon et al. (2007) provided weekly feedback messages by e-mail to all participants regarding their reported self-monitoring behaviors. Two studies provided tailored feedback to participants according to their performance in reaching their setting goals (Burke et al., 2010; Lee W. et al., 2010). Some studies lacked instant feedback (Yon et al., 2007; Lee C. et al., 2010) but did send weekly reminders and encouragement to participants.

### **Satisfaction with technology**

The majority of studies reported great users' satisfaction with technology (Joo and Kim, 2007;; Morak et al., 2008; Haapala et al., 2009; McGrievy et al., 2009; Patrick et al., 2009; Burke et al., 2010; Lee C. et al., 2010; Lee W et al., 2010). McGrievy et al. (2011) reported that mobile technology enhanced social support in the experimental group and made them more likely to use mobile social networking, in comparison to the control group that relied mainly on friends for support.

### **Exercise**

Mattila et al. (2010) found that higher amount of time spent in weekly exercise was positively correlated with weight loss. Other studies did not find that the use of mobile technology enhanced physical activity in the experimental versus the control group (Yon et al., 2007; McGrievy et al., 2009).

## **IMPLICATIONS FOR RESEARCH**

Mobile technology is an evolving field of research that holds the promise of an innovative channel for healthcare interventions delivery. The majority of study findings support the utility of mobile technology to deliver tailored weight loss interventions based on individual

assessment. This can be promising, since even a small percentage of weight loss of 5 to 10% of initial body weight can have substantial health benefits (DPP, 2002). Self-monitoring diet and exercise, feedback and adherence to technology were positively correlated with weight loss. Satisfaction with the mobile technology enhanced the perceived social support in its users. Healthcare providers should therefore be well versed of the unlimited health avenues that can be accessed through mobile technology in order to guide and advocate for patients when choosing a mobile technology that best suits their lifestyle. Overweight and obese subjects might benefit from weight loss behavioral intervention administered through mobile technology using mainly SMS or mobile health applications.

### **RISK OF BIAS**

The quality and strength of evidence of selected studies was evaluated independently by two researchers against criteria for assessment of risk of bias proposed by the Cochrane back review group (Furlan et al., 2009). Each criterion was rated either “yes, unclear, or no” to indicate if the criterion has been met. In order for a study to be rated as having a "low risk of bias" it should meet at least 6 out of the 12 criteria and does not include a serious flaw. Studies which met less than six criteria were considered to have a "high risk of bias". These criteria apply only to RCTs. Other studies using within subjects design, pre- post interventions, were assessed by questions derived from the Critical Appraisal Skills Program appraisal checklist tool (CASP) available from Wales University ([Http://hebw.cf.ac.uk/methodology/appendix11.htm](http://hebw.cf.ac.uk/methodology/appendix11.htm)). Risk of bias for RCTs were presented in table 2 and the studies quality coding criteria in table 3.

The majority of the studies associated more than one behavioral and mobile technology components, thus making it difficult to isolate the real effect of each component on weight loss. Participants in these studies presented wide heterogeneity in regard to age (18 – 70 years), BMI



(25 – 40kg/m<sup>2</sup>) and socio-economic status. Most participants were classified as white and holding at least a high school education, making findings difficult to generalize to other population. In this review, there were few long-term interventions that are necessary to determine the true effect of mobile technology on body weight since weight regain among participants is common. The strength of the evidence in the current review might be affected by the excluded studies due to participants having an underlying disease. Studies related to childhood and adolescent obesity, were not included due to a recent literature review covering this topic (Nguyen et al., 2011). Internet-based weight loss programs were not included as well, in order to focus on the mobile aspect of available technology.

In summary, it is difficult to calculate the true effect of interventions on weight loss in overweight and obese population due to the great heterogeneity between studies in regard to design, duration, population, theoretical framework and the variety of components used in mobile technology in conjunction to weight loss interventions.

## CONCLUSION

Although there is evidence supporting the utility of mobile technology in administering weight management interventions, findings from the current review should be interpreted with caution. SMS appears to be the most mobile technology component associated with weight loss. The wide heterogeneity of mobile technology components used in the selected studies and the inconclusive findings in this review, prevent drawing strong evidence regarding the most successful interventions for weight loss. Long-term interventions with large sample size, assessing one component of mobile technology at a time, are needed in order to build a strong body of knowledge.

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Table 1: Characteristics and findings of included review studies

Author, publication year	Description of intervention/ technology used	Participants Age, sample size, weight, BMI	Study design, assessment	Duration Attrition rate	Results
Patrick et al, 2009	Evaluating daily SMS via mobile phone to lose or maintain weight. The experimental group 1) Monthly printed material about weight loss. 2) Personalized SMS 2-5 times daily (with weekly different topic), printed materials & monthly phone call from counselor. Users report weight weekly. Control group received printed material each month	78 subjects 80% women BMI:25-39.9 kg/m <sup>2</sup> Age: 25-55 years	RCT  Assessment done at zero, two, and four months	4 months  attrition rate:17%	Intervention lost more weight than comparison (1.97 Kg) p = 0.02. Adherence declined at the end of the study.
Morak et al., 2008	Utility of mobile phones as subjects terminals to access obesity therapy. Subjects used cell phones to store info in a central database via internet. An individual therapy plan is generated based on data entry (nutrition + physical activity).	25 subjects: 10 male, 15 Female. Mean age: 48years mean BMI: 35.6	Within subjects comparison of mean at baseline and after 70 days	70 days  Attrition rate not stated	significant reduction in body weight : 2.4 kg (p<0.001) Majority reported positive attitude toward the system.
Burke et al., 2010	Evaluating the effect of self-monitoring with PDA use versus paper and pencil diaries on short & long term weight loss. Randomization to 3 groups: 1)standard paper record 2)PDA (diet+ physical activity software) 3) PDA (diet+ physical activity software) in addition to customized daily feedback. All participants received standard behavioral treatment	210 subjects. Mean age: 49 years Mean BMI: 34	RCTs with 3 groups. Assessment at baseline and at 6 months	6 months  Attrition rate: 8%	All groups had significant weight loss but weight loss did not differ among groups. Adherence to self-monitoring was higher in PDA's than paper group. Greatest weight loss was achieved in the PDA+ feedback group.

## Mobile Technology Strategies and Weight Management: A Systematic Review

Haapala et al., 2009	Evaluate short & long term effectiveness, predictors of weight loss using mobile phone program. Experimental group had mobile phone software sending tailored text messages for food reduction and daily weight reporting, and having instant feedback. Subjects can set their short and long-term weight goals. The control group had no intervention.	125 subjects randomized Age: 25-44 years BMI: 26-36 kg/m <sup>2</sup>	RCT Measurements at 0,3,6 and 12 months	12 months Attrition rate: 13.7%	Significant weight loss in experimental group at 3, 12 months as compared to control group, p=0.006. List of predictors of weight loss including early weight loss, contact frequency, self-efficacy
Author, publication year	Description of intervention/ technology used	Participants sample size, age, weight, BMI	Study design, assessment	Duration Attrition rate	Results
Lee W. et al., 2010	Effectiveness of mobile phone application "SmartDiet" on dietary info, weight control and user satisfaction. Application downloaded into mobile, provides customized meal & exercise plan; diet game promotes knowledge about nutrition.	Intervention= 19, control= 17. Age: 28-29 years Mean BMI: 22 kg/m <sup>2</sup>	Case control design.  At baseline and 6 weeks.	6 weeks Attrition rate: Not stated	Significant decrease in 3 body composition measures (fat mass, weight, BMI) in the intervention but not the control group (p<0.05).
Yon et al., 2007	Efficacy of PDA for self-monitoring weight loss in a behavioral program as compared to traditional diaries. Behavioral weight loss program with modification of eating (cutting 1000 kcal/day) & exercise habits (expending 1000 kcal/week = 10 miles /week), using behavioral strategies & self-management.	Intervention: 56 women, 5 men. mean age 48.2 y. mean BMI 32.3 Control: 96 women, 19 men. mean age 46.1 y mean BMI 30.9	Experimental versus control group. Assessment at baseline and 6 months.	6 months Attrition rate in experimental group: 7% In control group 17%	No significant difference in BMI between groups (p= 0.68). Self-monitoring was associated with weight loss in both groups p< .001. Adherence to self-monitoring correlated with significant weight loss p< 0.001. Adherence was higher in PDA groups versus paper group.
Joo& Kim 2007	Used mobile phone SMS feature for behavior modification in obesity treatment. Weekly SMS on behavior modification and an info brochure about exercise and diet sent by mail. Behavior strategy: exercise (30 min/day more than 4 times/week) and nutritional info: with 400-500 calories deficit/ day.	433 participants Women:89% Age range; 30-60 years Mean BMI: 25.7 kg/m <sup>2</sup>	within subject comparison Measured at baseline and 12 weeks	12 weeks Attrition rate 19%	Significant reduction of waist circumference, body weight and BMI at 12 weeks: p<0.05



## Mobile Technology Strategies and Weight Management: A Systematic Review

Mattila, et al., 2010	Use of a mobile phone diary application (app) for weight management and related behaviors. Measuring by self-report: weight, steps, exercise, food and drinks. Weekly data report sent to investigator. A reminder to participants to report data was sent weekly for any unreported data.	Female =8, Male =19 Age range: 25-54 years BMI range: 24.7-32.1	Within subject comparison. Assessment at baseline and 12 weeks.	12 weeks Attrition rate 10%	Significant correlation between weight loss and higher amount of exercise per week $p < 0.05$ Positive correlation between decrease in heavy meals, and increase in light snacks and weight loss $p < 0.05$ .
McDoniel et al., 2009	Evaluate a short term motivational effect of a technology-based weight reduction program in obese adults. Subjects were randomized into experimental (SMART: self-monitoring and resting metabolic rate technology) group and a control group who received the usual care.	11 obese (62% female) Mean BMI: 37 Mean age 45.5 y	RCT Assessment at 0, 4, and 12 weeks.	12 weeks Attrition rate 28%	No significant difference in bodyweight between groups overtime $p = 0.19$ .
Author, publication year	Description of intervention/ technology used	Participants sample size, age, weight, BMI	Study design, assessment	Duration Attrition rate	Results
McGrievy et al., 2009	Compare a theory based podcast for weight loss versus a commercially available weight loss podcast.	Intervention=41: mean age 37.7 y Control=37: mean age 39.6 y BMI: 25-40	RCT: 2 podcasts /week for 12 weeks. Control: podcast discussions how to lose weight	12 weeks Attrition rate 17%	Greater weight loss in the experimental than the control group $p < 0.001$ .
Cunningham B., 2011  Dissertation	Compare the efficacy of using smartphone self-monitoring app to track diet and exercise, versus paper and pencil diary. Subjects divided into 3 groups :( 1) phone app sending daily food log report to researcher. (2) Recorded food & exercise on the phone "memo" function and sent by e-mail daily. (3) Record on a notebook and return it at week 4 and 8.	57 subjects. Age:18-65 y BMI:25-40	Controlled experimental design.  Assessment at 0, 4, 8 weeks.	Duration 8 weeks.  Attrition rate: 15%	All groups had significant weight loss but, there was no significant difference between groups. The phone app group had a 40% higher recording rate compared to paper group and 23% higher than memo group.

## Mobile Technology Strategies and Weight Management: A Systematic Review

McGraa K., 2010 Dissertation	Explore the effect of persuasive motivational Text messaging on adherence to diet and exercise programs across different personality traits. The researcher sent a weekly e-mail to participants to ask them about their logging activity (food, exercise, stress, motivation, weekly weight) and expected a reply from participants. Experimental group received text messages, the control group did not.	65 subjects 80% female 20% male Age range 18-70 years BMI not stated.	controlled experimental design with subjects stratified to match for demographics	5 weeks Attrition rate 23%	There was no significant difference in total days of exercise between groups. No significant difference in BMI changes between groups. Different traits of personality did not predict weight gain.
Lee, C. et al, 2010	Determine the effect of a 12 weeks self-management intervention program (healthy diet and exercise, phone counseling and a SMS biweekly) versus a structured exercise management program with a three 1 hour walking class per week.	28 women in experimental with mean age 47 y, mean BMI 28.14 24 in control group mean age 45 y, mean BMI 27.84	Quasi-experimental. At baseline and at 12 weeks	12 weeks Attrition rate in exp.55%. In control group 54%.	Total exercise time increased in both groups with no significant difference between groups. BMI decreased in both groups but there was no statistical difference between groups.
McGrievy et al., 2011	Evaluation of the effects of a combination of podcasts, mobile support communication and mobile diet monitoring on weight loss. Control group: podcasts only. Experimental group: podcasts, mobile application to self-monitor diet and exercise, mobile application for social networking	96 subjects with 72 women. BMI (25-45 kg/m <sup>2</sup> ) Age (18-60 y)	RCT. Control: podcasts only Experimental: podcasts + enhanced mobile media intervention	6 months Attrition rate: 11% in exp , 10% in control group	At 6 months, there was no significant difference in weight loss between groups: p=0.88. There was no difference between groups in regard to diet monitoring and social support.

Table 3: Study quality coding criteria and appraisal of risk of bias for RCTs and quasi-experimental studies

Study	True randomization	Allocation concealment	Blinding subject & researcher	ITT	Attrition rate	Same group analysis	Objective outcome reporting	Baseline similarity	Separation of intervention effect	Compliance	Similar time for outcome assessment	Score %
McGraa K. 2010	No	No	Yes No	No	No	yes	yes	yes	yes	yes	yes	58%
Cunningham, 2011	No	No	Yes No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	67%
Lee C. 2010	No	No	No No	No	No	yes	Yes	Yes	No	yes	yes	41%
McDoniel Et al., 2009	yes	No	Yes No	yes	yes	yes	yes	yes	No	yes	Yes	83%
Burke et al., 2010	yes	no	Yes no	yes	yes	yes	Yes	yes	Yes	Yes	Yes	83%
Yon et al., 2007	No	No	No No	yes	yes	Yes	Yes	Yes	yes	yes	No	58%
Haapala et al., 2009	yes	yes	Yes yes	yes	yes	yes	yes	yes	yes	yes	yes	100%
McGreivy et al., 2009	Yes	No	No no	yes	yes	yes	Yes	Yes	Yes	Yes	yes	75%
Patrick et al., 2008	yes	No	No No	yes	yes	Yes	Yes	Yes	Yes	Yes	Yes	75%
McGrievy et al. 2011	Yes	No	No No	yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	75%

Table 4: Study quality coding criteria and appraisal for other intervention designs (within subjects' comparison)

Study	Aims stated	Selection Criteria	Presence of control group	Tables & Graphs	Appropriate Statistical methods	Support of conclusions	Applicability of results to community	Consideration Of all outcomes	Separation of intervention effect	Score %
Mattila et al., 2010	Yes	No	N/A	Yes	Yes	Yes	No	Yes	N/A	71%
Morak et al., 2008	Yes	No	N/A	yes	Yes	Yes	No	Yes	N/A	71%
Lee, W. et al., 2010	yes	no	yes	Yes	Yes	Yes	No	Yes	Yes	78%
Joo et al., 2007	Yes	No	N/A	Yes	Yes	Yes	No	Yes	N/A	71%

## VCU IRB FULL and EXPEDITED STUDY INITIAL REVIEW SUBMISSION FORM

IRB NUMBER: \_\_\_\_\_

### DO NOT DELETE SECTIONS OF THIS FORM

#### SECTION 1: PRINCIPAL INVESTIGATOR AND OTHER VCU PROJECT PERSONNEL

##### 1. PRINCIPAL INVESTIGATOR: LIST NAME AS IT EXISTS IN THE HUMAN RESOURCE SYSTEM (HRS)

**NOTE:** See guidance on who can serve as PI at [HTTP://WWW.RESEARCH.VCU.EDU/IRB/WPP/FLASH/IX-1.HTM](http://www.research.vcu.edu/irb/wpp/flash/ix-1.htm)

Name (Last, First, MI): Salyer, Jeanne

PI Title and Degrees: RN, PhD

VCU Department: Adult Health and Nursing Systems

VCU P.O. Box #

(must provide 6-digit box #):

Phone/Pager/Fax #'s: **PHONE: 828-3373; FAX# 828 7743**

VCU Email: **JSAYLER@VCU.EDU**

##### 2. PROJECT PERSONNEL TO BE

##### INCLUDED IN CORRESPONDENCE:

These persons may be copied on correspondence from the IRB.

(ALL project personnel are to be listed on a separate *VCU IRB Study Personnel Roster*)

##### RESEARCH COORDINATOR (if applicable):

Name (Last, First, MI), Degrees:

Email:

##### TRAINEE (Postdoctoral Scholar, Fellow or Resident) (if trainee project):

Name (Last, First, MI), Degrees:

Email:

##### STUDENT (if student project):

Name (Last, First, MI), Degrees: (BOUHAI DAR, CLAUDIA H.) RN, MS.

Email:

BOUHAI DARCM@VCU.EDU

#### SECTION 2: PROJECT INFORMATION

##### 1. PROJECT TYPE (check one):

**BIOMEDICAL**

Research involving medical interventions and/or FDA-regulated products

**SOCIAL-BEHAVIORAL (check one):**

Social or behavioral research that does **NOT** involve medical interventions or FDA-regulated products

**SOCIAL-BEHAVIORAL QUALITATIVE**

**SOCIAL-BEHAVIORAL QUANTITATIVE**

**SOCIAL-BEHAVIORAL QUALITATIVE**

**& QUANTITATIVE**

##### 2. TITLE OF PROTOCOL SUBMISSION:

MOBILE PHONE TEXT MESSAGING AS ADJUNCT TO A COMMUNITY-BASED WEIGHT MANAGEMENT PROGRAM

##### 3. Are there any **IRB-APPROVED PROTOCOLS ASSOCIATED** with this submission?

YES

NO

If YES, please list the associated VCU IRB Protocol #'s:

**Note:** If this submission is associated with other new projects submitted to the IRB (but not yet approved), please attach a cover memo to your submission noting related projects.

##### 4. Is this a **TRAINEE OR STUDENT PROJECT** in which activities will be carried out by that individual under your supervision?

YES

NO

### SECTION 3: TYPE OF SUBMISSION

Please check all categories that apply to the study being submitted for IRB review.

**RESEARCH PROJECT**

**FDA REGULATED RESEARCH\***

\* FDA regulated research includes:

- a) any research involving a drug or biologic intended for human use (other than the use of an approved drug in the course of medical practice);
- b) any research designed to test the safety and effectiveness of a device; or
- c) research involving ANY FDA regulated product where the intent is to submit data to the FDA in support of a research or marketing application. Regulated products include foods & dietary supplements, infant formulas, food & color additives, and electronic products.

**CLINICAL TRIAL**

See definition of clinical trial at <http://www.cto.vcu.edu/about/index.html#ClinicalTrialDefinition>

**HUMANITARIAN USE DEVICE**

See guidance at <http://www.research.vcu.edu/irb/wpp/flash/XVI-2.htm>

**TREATMENT USE OF INVESTIGATIONAL DRUG/DEVICE**

See guidance at <http://www.research.vcu.edu/irb/wpp/flash/XVI-5.htm>

### SECTION 4: TYPE OF REVIEW

**REVIEW TYPE REQUESTED (check one):**

**FULL BOARD REVIEW**

**NOTE:** Industry-sponsored research **MUST** be submitted to Western IRB (WIRB) for review. See instructions available at <http://www.research.vcu.edu/forms/wirb.htm>

**EXPEDITED REVIEW**

\* **EXPEDITED CATEGORIES:** 7

\* Identify the expedited category or categories in which your research falls (See Expedited Review Guidance at <http://www.research.vcu.edu/irb/reviewtypes.htm>)

**NOTE:** For projects requesting exempt review determination, use the exempt review submission form, available at <http://www.research.vcu.edu/forms/vcuirb.htm>.

### SECTION 5: SPONSOR DATA

1. Does the research project involve a **DIRECT FEDERAL AWARD** made to VCU (or a research funding proposal for such)?  YES  NO

2. Have you submitted a related research funding proposal(s) to the VCU Office of Sponsored Programs (OSP)?  YES  NO

If YES, you must provide (a) **NAME OF THE FUNDING SOURCE AND (b) PT/PD #** for each related proposal (**regardless of the funding source**):

(1) (2) (3)

**NOTE:** Federal regulations require IRB approval of **NEW**, **RESUBMISSION**, or **COMPETING CONTINUATION** FEDERAL RESEARCH FUNDING PROPOSALS. If there is a new, resubmission, or competing continuation VCU federal research funding proposal associated with this research project, you must include a copy of your ENTIRE proposal (exclusive of appendices) and OSP Internal Approval Form with this submission. Failure to do so may delay your research award start date. Other sponsors also may require IRB approval of research proposals. It is the investigator's responsibility to determine whether this review is needed. If the sponsor does not require IRB approval of research proposals, DO NOT submit them to the IRB for review. If you have questions about whether your sponsor requires IRB approval of your research funding proposal, please contact OSP.

## SECTION 6: STATEMENTS OF COMPLIANCE

### **PRINCIPAL INVESTIGATOR STATEMENT OF COMPLIANCE:**

I understand and accept responsibility for ensuring the safety and welfare of all human subjects who participate in the proposed research project. I certify that all key project personnel, including myself, sub/co-investigators, research coordinators, trainees, and students have completed the VCU required training on human subjects protection. I agree to a continuing exchange of information with the VCU IRB including the requirements to (i) obtain IRB approval before making non-emergency changes/revisions to the project, except where necessary to eliminate apparent immediate hazards to subjects or others, (ii) provide progress reports to the VCU IRB at their request (and at least annually), and (iii) report promptly to the IRB all unanticipated problems and serious adverse events involving risk to human subjects (in accordance with required reporting timelines by the IRB).

**SIGNATURE OF INVESTIGATOR:** \_\_\_\_\_

**DATE OF SIGNATURE:** \_\_\_\_\_

### **TRAINEE OR STUDENT INVESTIGATOR STATEMENT OF COMPLIANCE (IF APPLICABLE):**

This is a student or trainee project, which will potentially be presented outside the classroom and/or published. I understand that I may not proceed with the research without first receiving a formal written letter of approval from the VCU IRB. I certify that I have completed the VCU required training on human subjects protection.

**SIGNATURE OF TRAINEE OR STUDENT:** \_\_\_\_\_

**DATE OF SIGNATURE:** \_\_\_\_\_

### **DEPARTMENT/DIVISION CHAIRPERSON OR DEAN STATEMENT OF COMPLIANCE\*see NOTE:**

I certify that the research project referenced in this document (check one of the following):

- Has been subjected to scrutiny within a VCU Committee (i.e., Massey Cancer Center Protocol Review, Clinical Research Center [CRC]) or sponsor study group (i.e., NIH or other agency with appropriate scientific expertise) and found to be scientifically acceptable.
- Has been subjected to scrutiny by my designee or me according to criteria that include the following, as applicable: appropriate power and sample size, currency of literature review, and relevance of hypothesis or research question and found to be scientifically acceptable.

**PRINT NAME, DEGREES, TITLE OF DEPARTMENT/DIVISION CHAIRPERSON OR DEAN:** \_\_\_\_\_

**SIGNATURE OF DEPARTMENT/ DIVISION CHAIRPERSON OR DEAN:** \_\_\_\_\_

**DATE OF SIGNATURE:** \_\_\_\_\_

**\*NOTE:** Department/Division Chairperson cannot sign if he/she is a co-investigator on the project. In these instances, a Dean's signature is required. If a designee is signing the Statement of Compliance, his/her name, degrees, and title should be listed.

## SECTION 7: PROJECT DETAIL

ANSWER ALL OF THE FOLLOWING QUESTIONS (by marking the appropriate box to the right):

**1. Will DRUG(S), BIOLOGIC(S), OR DEVICE(S) be utilized for this project?**  YES  NO\*  
**If NO, skip to Question 7.**

**2. Will DRUG(S) be administered in this project?** If YES, supply the following information  YES  NO  
 (attach a separate sheet if necessary):

**DRUG NAME(S):** \_\_\_\_\_

**2-A. If drug is INVESTIGATIONAL or involves an IND, please complete the following:**

**IND #:** \_\_\_\_\_ **HELD BY (check one):**  SPONSOR  INVESTIGATOR  N/A

- If IND is held by the SPONSOR, provide copy of the INVESTIGATOR'S BROCHURE and the SPONSOR'S PROTOCOL
- If IND is held by the INVESTIGATOR, provide copy of the IND APPLICATION submitted to the FDA and safety information
- Attach copy of FDA FORM 1572

**3. Will BIOLOGIC AGENTS be used in this project?** If YES, supply the following information:  YES  NO

**BIOLOGIC NAME(S):** \_\_\_\_\_

**4. Will the VCU/VCUHS INVESTIGATIONAL DRUG SERVICE PHARMACY (IDS) be utilized? (required for all inpatient projects)**  N/A\*\*  NO\*

\*If NO, you must submit a descriptive plan regarding appropriate drug storage and dispensing for an investigational drugs or biologic agents/drugs used in the research to the Investigational Drug Service (IDS) Pharmacy. Guidance and the form for describing the management plan is located at <http://www.investigationaldrugs.vcu.edu>. Submit the form to the IDS. Upon IDS's receipt of the plan, an email response containing the plan is generated. Include the IDS confirmation or receipt with this submission. For assistance, please call the Investigational Drug Pharmacy at 828-7901.

\*\*Submitting a plan to the IDS is not required if: 1) no drugs are used in the study, 2) the drug used in the study is FDA-approved, considered standard of care and is a patient-charge item, 3) off-label use of such a drug is not being studied and 4) there is no protocol requirement for specific management of the drug.

**5. Are you evaluating MARKETED MEDICAL DEVICE(S) (including 510k devices) in this project?** If YES, supply the following information:  YES  NO

**DEVICE NAME(S):** \_\_\_\_\_

**NAME OF MANUFACTURER:** \_\_\_\_\_

**NOTE:** In addition, provide any supporting documentation regarding LEVEL OF RISK (SIGNIFICANT vs. NON-SIGNIFICANT RISK)

**6. Are you evaluating INVESTIGATIONAL MEDICAL DEVICE(S) or a NEW USE FOR MARKETED MEDICAL DEVICE(S) in this project?** If YES, supply the following information:  YES  NO

**DEVICE NAME(S):** \_\_\_\_\_

**NAME OF MANUFACTURER:** \_\_\_\_\_

**IDE #:** \_\_\_\_\_ **HELD BY (check one):**  SPONSOR  INVESTIGATOR  N/A

- If IDE is held by the SPONSOR, provide a copy of the INVESTIGATOR'S BROCHURE and the SPONSOR'S PROTOCOL
- If IDE is held by the INVESTIGATOR, provide a copy of the IDE APPLICATION submitted to the FDA

**NOTE:** In addition, provide any supporting documentation regarding LEVEL OF RISK (SIGNIFICANT vs. NON-SIGNIFICANT risk)



**7-A. Does this project involve the use of any procedure(s) that will expose the research subject to IONIZING RADIATION?**

YES (Proceed to 7-B)

NO (Proceed to Question 8)

**7-B. If all of these procedures are for the direct clinical benefit of the research subject/patient, check YES. If any of these procedures are of research interest only and will not affect the clinical management of the research subject, check NO.**

YES (no further information required)

NO (Proceed to 7-C)

**7-C. RADIATION SAFETY COMMITTEE (RSC) approval is required if you answered NO to item 7-B. Do you have RSC approval for this project?**

YES (Attach copy of RSC Approval Letter)

NO (Contact the Radiation Safety Section at 828-9131 for approval information)

**NOTE:** See also <http://www.vcu.edu/oehs/radiation/humanuseguide.pdf>

**8-A. Does this project involve the use of RECOMBINANT DNA, BIO-HAZARDOUS SUBSTANCES including pathogenic or potentially pathogenic viruses and bacteria (e.g., Adenovirus, HIV, Hepatitis B), CARCINOGENS OR ACUTE CARCINOGENS, MUTAGENS, TERATOGENS, ACUTE TOXINS, OR SELECT AGENT MATERIALS?**

YES (Proceed to 8-B)

NO (Proceed to Question 9)

**8-B. INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) approval is required if you answered YES to this question. Do you have IBC approval for this project?**

YES (Attach copy of IBC Approval Letter)

NO (Contact CHEMICAL AND BIOLOGICAL SAFETY OFFICE at 828-4866 for approval information)

**NOTE:** See also <http://www.vcu.edu/oehs/chemical/>

**9. Does this project involve GENE THERAPY?**

YES

NO

**10-A. Does this study involve cancer patients, their families, or their health care providers?**

YES \*

NO

**10-B. Is this a Cancer Prevention Study?**

YES \*

NO

\* If YES TO 10-A OR 10-B, the research project must be reviewed and approved by the MASSEY CANCER CENTER PROTOCOL REVIEW AND MONITORING COMMITTEE before IRB Review, and a copy of the approval letter provided. For information, see <http://www.massey.vcu.edu/research/?pid=2013> or call the PRMC Coordinator at 628-1924.

**11. Will this project be conducted in the CLINICAL RESEARCH CENTER (CRC)?**

YES \*

NO

\* If YES, please review information for investigators available at <http://www.vcuhealth.org/crc/>

**12. Is your project: (1) involving human subject activities conducted by Navy and Marine Corps personnel; (2) involving naval military personnel and Department of Navy (DoN) employees as research subjects; (3) supported by naval activities through any agreement (e.g., contract, grant cooperative agreement, development agreement [CRADSs], or other arrangement), regardless of the source of funding, funding appropriation, nature of support, performance site, or security classification; or (4) using DoN property, facilities or assets?**

YES \*

NO

\* If YES, you must ensure that your project meets the additional Department of Defense (DoD)-Department of the Navy (DoN) requirements for human subject protection. Guidance on additional requirements can be found at [<http://www.research.vcu.edu/irb/wpp/flash/XVII-12.htm>]

**13. Will this project be conducted in a VCUHS patient care area or involve VCUHS patients?**

YES\*

NO

\*If YES, I have reviewed and agree to comply with the CONDUCT OF CLINICAL RESEARCH IN VCU HEALTH SYSTEM PATIENT CARE AREAS policy on this page: <http://www.research.vcu.edu/irb/guidance.htm>.

**14. HIPAA Regulatory Compliance****14-A. Will this study use or access protected health information (PHI)?\*** YES  NO\*\*\*See Decision Tree 1: Determining when HIPAA Applies to Research at <http://www.research.vcu.edu/irb/hipaa-guidance.htm>

\*\*If no, go to Question 15

**14-B. Select all of the ways PHI will be used for this study.**

- Determine study feasibility [COMPLETE REVIEW PREPARATORY TO RESEARCH FORM]
- Identify and recruit potential study participants from within the VCUHS system or other covered entity [COMPLETE APPENDIX A: HIPAA FOR RESEARCH]
- Collected and maintained in medical record or research records (prospective collection) [COMPLETE APPENDIX A: HIPAA FOR RESEARCH]
- Collected from medical records within the VCUHS system or other covered entity (retrospective collection) [COMPLETE APPENDIX A: HIPAA FOR RESEARCH]

Access HIPAA guidance information here: <http://www.research.vcu.edu/irb/hipaa-guidance.htm>**15. Does this project involve the creation of or contribution to a Research Registry?** (A registry is an organized collection of retrievable, identifiable information (pertaining to living humans) that is intentionally maintained for use as a prospective instrument for the conduct of research.) YES\*  NO\*\*\* If YES, you must follow guidance at <http://www.research.vcu.edu/irb/wpp/flash/XVII-4.htm> and answer 15-A and 15-B.

\*\*If NO, skip to Question 16

**15-A. Will the registry be maintained at VCU?** YES  NO**15-B. Does the registry include any identifiers?** YES  NOSee list of 18 identifiers here: <http://www.research.vcu.edu/irb/hipaa-guidance.htm>**16. Do you plan to involve NON-VCU INSTITUTIONS (i.e., institutions [or employees or agents of the institutions] that are not under the authority of VCU or VCU Health Systems and are located within the United States or a United States territory) in your research project?** YES \*  NO\* If YES, you must follow guidance at <http://www.research.vcu.edu/irb/wpp/flash/XVII-6.htm>**17. Do you plan to involve FOREIGN RESEARCH SITES (i.e., institution or non-institutional setting)?** YES \*  NO\* If YES, you must follow guidance at <http://www.research.vcu.edu/irb/wpp/flash/XVII-11.htm>**18. Do you plan to involve INDEPENDENT INVESTIGATORS (i.e., individuals who are not representatives of VCU or any other institution or facility) in your research project?** YES \*  NO\* If YES, you must follow guidance at <http://www.research.vcu.edu/irb/wpp/flash/XVII-15.htm>**19. Does this project involve GENETIC TESTING, that is, testing human tissue samples for heritable characteristics or storing human tissue samples for possible future such testing?** YES \*  NO\* If YES, you must follow guidance at <http://www.research.vcu.edu/irb/wpp/flash/XVII-5.htm>**SECTION 8: RESEARCH SUBJECT INFORMATION****VULNERABLE SUBJECTS:****1. Do you plan to allow for the inclusion of data on subjects who are children?** YES \*  NO

\* If YES, include the VCU IRB CHILDREN-SUBJECT FORM with your submission. The form is available at

<http://www.research.vcu.edu/forms/vcuirb.htm>**NOTE:** In Virginia, children are those under the age of 18 and not emancipated.**2. Do you plan to allow for the inclusion of data on subjects who are PREGNANT WOMEN, HUMAN FETUSES, or NEONATES?** YES \*  NO

\* If YES, include the VCU IRB PREGNANT WOMEN, FETUSES, NEONATES-SUBJECT FORM with your submission. The form

is available at <http://www.research.vcu.edu/forms/vcuirb.htm>

3. Do you plan to allow for the inclusion of data on subjects who are, or may become a PRISONER?  YES \*  NO

\* If YES, you must follow the VCU IRB PRISONER-SUBJECT GUIDANCE and include the VCU IRB PRISONER-SUBJECT FORM with your submission. The guidance and form are available at <http://www.research.vcu.edu/forms/vcuirb.htm>

### SUBJECT ENROLLMENT PLAN:

**Anticipated # OF SUBJECTS** (if this is a multi-center project, list only subjects under this IRB approval): 30

Is this a **MULTI-CENTER PROJECT**?  YES  NO

If YES, please provide:

(1) # OF SITES:

(2) # OF SUBJECTS ACROSS ALL SITES:

**CONSENT DOCUMENTATION:** (Mark the type of consent process/documentation planned):

- STANDARD CONSENT FORM:** A copy of the proposed consent form(s) is attached to this submission.
- CONSENT FORM FOR PRISONER SUBJECTS:** A copy of the proposed consent form for prisoners is attached to this submission.
- WAIVER OF SOME OR ALL ELEMENTS OF CONSENT OR PARENTAL PERMISSION:** **NOTE:** Waiver is not allowed for FDA-regulated research unless it meets FDA requirements for Waiver of Consent for Emergency Research (see below). A request is being made to waive the requirement to obtain prospective informed consent from subjects or permission from parents. Your research synopsis should explain why: (1) the research involves no more than minimal risk to the subjects, (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects, (3) the research could not practicably be carried out without the waiver or alteration; **AND** (4) whether or not subjects will be debriefed after their participation. Guidance is available at <http://www.research.vcu.edu/irb/wpp/flash/XI-1.htm>.
- WAIVER OF DOCUMENTATION OF CONSENT, PARENTAL PERMISSION:**  
A request is being made to waive documentation of consent. The IRB may waive this requirement if it finds either: (1) that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Subjects will be asked whether they want documentation linking them with the research, and each subject's wishes will govern; or (2) that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Your research synopsis should include a justification for waiver based on one of these two elements and include a description of the information that will be provided to participants. If you are proposing to use a verbal consent statement, the proposed consent script should be attached to this submission. Guidance is available at <http://www.research.vcu.edu/irb/wpp/flash/XI-2.htm>
- ASSENT FORM:** A copy of the assent form for children or decisionally-impaired persons is attached to this submission. Guidance is available at <http://www.research.vcu.edu/irb/wpp/flash/XV-2.htm>. and <http://www.research.vcu.edu/irb/wpp/flash/XVII-7.htm>.
- WAIVER OF ASSENT:** A request is being made to waive the requirement to obtain prospective assent from children age 7 or higher, or decisionally-impaired persons. Your research synopsis should explain (1) why some or all of the individuals age 7 or higher, or decisionally-impaired will not be capable of providing assent based on their developmental status or impact of illness; (2) the research holds out a prospect of direct benefit not available outside of the research; **AND/OR** (3) [a] the research involves no more than minimal risk to the subjects, [b] the waiver or alteration will not adversely affect the rights and welfare of the subjects, [c] the research could not practicably be carried out without the waiver or alteration; **AND** [d] whether or not subjects will be debriefed after their participation. Guidance is available at <http://www.research.vcu.edu/irb/wpp/flash/XV-2.htm>.
- WAIVER OF CONSENT FOR EMERGENCY RESEARCH:** Guidance is available at <http://www.research.vcu.edu/irb/wpp/flash/XVII-16.htm>.

## SECTION 9: VCU RESEARCH PLAN

You must use the VCU Research Plan Template that can be found at <http://www.research.vcu.edu/forms/vcuirb.htm>. Use of this template is required to provide your VCU Research Plan to the IRB. Your responses should be written in terms for the non-scientist to understand. If a detailed research protocol (e.g., sponsor's protocol) exists, you may reference that protocol by including the specific location (section # or small page range) within the protocol where the requested information can be found.

**NOTE: If that protocol does not address all of the issues outlined in each Section Heading, you must address the remaining issues in this Plan. It is NOT acceptable to reference a research funding proposal.**

**NOTE:** A roster of all study personnel is to be provided utilizing a *VCU IRB Study Personnel Roster*. Information regarding each study personnel is to be submitted using the *VCU IRB Study Personnel Information and Change Form*. These forms can be found at <http://www.research.vcu.edu/forms/vcuirb.htm>.

## SECTION 10: SUBMISSION CHECKLIST

The following elements are reminders of steps and documentation that must be included with your submission packet.

**NOTE: If required documents are missing and multi-page documents are not individually stapled or clipped, your review may be delayed.**

**This checklist must be included as the last page of the IRB INITIAL REVIEW SUBMISSION FORM**

If not applicable, indicate "N/A."

- 1. VCU IRB INITIAL REVIEW SUBMISSION FORM**
- 2. VCU RESEARCH PLAN**  
Required with ALL submissions and MUST follow the template and include version number or date, and page numbers [see SECTION 9 of this form]. Review of your protocol will be delayed if the template is not followed.  
**NOTE: A research funding proposal cannot substitute for the VCU Research Plan**
- 3. VCU IRB STUDY PERSONNEL INFORMATION AND CHANGE FORM**  
Required with ALL submissions and MUST be completed for each project personnel [see SECTION 9 of this form].
- 4. VCU IRB STUDY PERSONNEL ROSTER**  
Required with ALL submissions and MUST follow the template and include version number or date, and page numbers [see SECTION 9 of this form].
- 5. MEASURES (e.g., surveys, questionnaires, instruments, appendices)**  
Measures MUST include title, version number or date, and page numbers
- N/A **6. SPONSOR'S PROTOCOL**  
If a sponsor's protocol exists, it must be submitted with the VCU Research Synopsis.  
**NOTE: A research funding proposal is not considered a Sponsor's protocol**
- N/A **7. ADVERTISEMENTS/SUBJECT RECRUITMENT MATERIALS**  
If approval is sought for advertisement/subject recruitment materials at this time. Materials MUST include version number or date
- 8. INFORMED CONSENT/ASSENT DOCUMENT(S)**  
Informed consent document(s) should follow a version of the VCU IRB CONSENT TEMPLATE and MUST include version number or date, and page numbers
- N/A **9. VCU IRB CHILDREN-SUBJECT FORM**
- N/A **10. VCU IRB PREGNANT WOMEN, FETUSES, AND NEONATES-SUBJECT FORM**
- N/A **11. VCU IRB PRISONER-SUBJECT FORM**

- N/A **12. FDA FORM 1572**  
If investigational drugs are involved in the research
- N/A **13. INVESTIGATIONAL DRUG PHARMACY PLAN**  
If a drug or biologic agent/drug will be used in the research and IDS will not be used, confirmation from IDS that a plan has been received is required with this submission [see SECTION 7(4) of this form]
- N/A **14. IND OR IDE APPLICATION**  
If a drug or device is used in the project and IND or IDE is held by the investigator [see SECTION 7(2) or 7(6) of this form]
- N/A **15. INVESTIGATOR'S BROCHURE**  
If a drug or device is used in the project and the IND or IDE is held by the sponsor [see SECTION 7(2) or 7(6) of this form]
- N/A **16. DOCUMENTATION REGARDING LEVEL OF RISK (when evaluating a device)**  
If an investigational medical device or a new use for marketed medical device is being evaluated [see SECTION 7(5) or 7(6) of this form]
- N/A **17. RADIATION SAFETY COMMITTEE APPROVAL** If required [see SECTION 7(7) of this form]
- N/A **18. INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW** If required [see SECTION 7(8) of this form]
- N/A **19. MASSEY CANCER CENTER PROTOCOL REVIEW AND MONITORING SYSTEM APPROVAL**  
If required, [see SECTION 7(10) of this form]
- 20. CONFLICT OF INTEREST DISCLOSURE STATEMENT**  
This form and explanatory supplement (if applicable) is required for the PI and all others who have responsibility for the design, conduct, or reporting of the research.
- N/A **21. RESEARCH FUNDING PROPOSAL**  
If required [see SECTION 5 of this form] The entire proposal (exclusive of appendices) and VCU Office of Sponsored Programs (OSP) Internal Approval Form must be included.
- 22. PRINCIPAL INVESTIGATOR CV (not to exceed 5-6 pages) or a BIOSKETCH (2-3 pages)**  
If submitting a biosketch, the NIH biosketch form (398) must be used. The biosketch form is available at <http://grants.nih.gov/grants/funding/phs398/biosketch.pdf>. Additional instructions are available at <http://grants1.nih.gov/grants/funding/phs398/phs398.html>.
- 23. CV OF DOCTORAL STUDENT, POSTDOCTORAL SCHOLAR, FELLOW, OR RESIDENT (not to exceed 5-6 pages) or a BIOSKETCH (2-3 pages)**
- N/A **24. MEDICALLY RESPONSIBLE INVESTIGATOR CV (not to exceed 5-6 pages) or a BIOSKETCH (2-3 pages)**
- N/A **25. REVIEW PREPARATORY TO RESEARCH FORM** If required [see SECTION 7(14) of this form]
- 26. APPENDIX A: HIPAA FOR RESEARCH** If required [see SECTION 7(14) of this form]
- 27. OTHER:** \_\_\_\_\_

**In addition, please ensure the following:**

- All key project personnel, including the principal investigator, sub/co-investigators, project coordinators, and students have completed **VCU REQUIRED TRAINING ON HUMAN SUBJECTS PROTECTION**. The exam can be accessed from the following website <http://www.research.vcu.edu/irb/education.htm>
- Principal Investigator, Trainee or Student (if applicable) and Department/Division Chairperson or Dean have **SIGNED THE APPROPRIATE STATEMENTS OF COMPLIANCE** [see SECTION 6 of this form]
- The **REVIEW TYPE REQUESTED** [see SECTION 4 of this form] has been checked

## NUMBER OF COPIES REQUIRED

**NOTE:** If required documents are missing, multi-page documents are not individually stapled or clipped, or the documents are not provided in the order noted below, your review may be delayed.

Double-sided documents are encouraged; but it is recommended that one (original) copy of consent/assent forms and recruitment documents be submitted as single sided to ensure that documents returned to the PI with an IRB approval stamp are legible.

**I.** If review type requested is **EXPEDITED**, submit **(4) COLLATED SETS** containing the following documents in the order noted.

- 1) VCU IRB Initial Review Submission Form
- 2) VCU Research Plan
- 3) Appendix A: HIPAA for Research
- 4) VCU IRB Study Personnel Information and Change Form(s)
- 5) VCU IRB Study Personnel Roster
- 6) Sponsor's Protocol (if applicable)
- 7) Advertisements/Subject Recruitment Materials (if applicable)
- 8) Informed Consent/Assent Documents(s) (if applicable) (**NOTE:** If this is a DHHS protocol, you **MUST** include the DHHS-approved consent/assent documents)
- 9) VCU IRB Children-Subject Form (if applicable)
- 10) VCU IRB Pregnant Women, Fetuses, Neonates-Subject Form (if applicable)
- 11) VCU IRB Prisoner-Subject Form (if applicable)
- 12) Confirmation of receipt of management plan from Investigational Drug Pharmacy (if applicable)
- 13) FDA Form 1572 (if applicable)
- 14) IND or IDE Application (if applicable)
- 15) Investigator's Brochure (if applicable)
- 16) Radiation Safety Committee Approval Letter (if applicable)
- 17) Massey Cancer Center Protocol Review and Monitoring System Approval Letter (if applicable)
- 18) Conflict of Interest Disclosure Statement (s) and supplement(s) if applicable
- 19) Research Funding Proposal (if applicable)
- 20) Principal Investigator CV or Biosketch
- 21) CV of Doctoral Student, Postdoctoral Scholar, Fellow, or Resident (if applicable)

**II.** If review type requested is **FULL BOARD**, follow the instructions below:

**A) All Full Board Initial Review submissions will undergo a pre-review process** - Submit 1 **COLLATED SET** containing the following documents for the **pre-review** process:

- 1) VCU IRB Initial Review Submission Form (signatures are not required for pre-review)
- 2) VCU Research Plan
- 3) Appendix A: HIPAA for Research
- 4) VCU IRB Study Personnel Information and Change Form(s)
- 5) VCU IRB Study Personnel Roster
- 6) Sponsor's Protocol (if applicable)
- 7) Advertisements/Subject Recruitment Materials (if applicable)
- 8) Informed Consent/Assent Document(s) (if applicable) (**NOTE:** If this is a DHHS protocol, you **MUST** include the DHHS-approved consent /assent documents)
- 9) VCU IRB Children-Subject Form (if applicable)
- 10) VCU IRB Pregnant Women, Fetuses, Neonates-Subject Form (if applicable)
- 11) VCU IRB Prisoner-Subject Form (if applicable)
- 12) Conflict of Interest Disclosure Statement. Submit Conflict of Interest Disclosure Statement **AND** Disclosure Supplement Form(s) IF any of the investigators answered YES to one of the questions. Signatures are required.
- 13) Principal Investigator CV or Biosketch
- 14) FDA Form 1572 (if applicable)
- 15) IND or IDE Application (if applicable)
- 16) Investigator's Brochure (if applicable)
- 17) Documentation of Level of Risk (if applicable)
- 18) Radiation Safety Committee Approval Letter (if applicable)

- 19) Massey Cancer Center Protocol Review and Monitoring System Approval Letter (if applicable)
- 20) Confirmation of receipt of management plan from Investigational Drug Pharmacy (if applicable)
- 21) Research Funding Proposal (if applicable)
- 22) Medically Responsible Investigator CV or Biosketch (if applicable)
- 23) CV of Doctoral Student, Postdoctoral Scholar, Fellow, or Resident (if applicable)

**AND**

**B) Once all outstanding items are addressed through the pre-review process and you have received confirmation that the submission is considered complete - Submit 25 COLLATED SETS containing the following documents (only 4 of the 25 sets need to include the documents noted in items 11-22 below):**

- 1) VCU IRB Initial Review Submission Form (signatures are required - 25 copies)
- 2) VCU Research Plan (25 copies)
- 3) VCU IRB Study Personnel Information and Change Form(s) (25 copies)
- 4) VCU IRB Study Personnel Roster (25 copies)
- 5) Sponsor's Protocol (if applicable – 25 copies)
- 6) Advertisements/Subject Recruitment Materials (if applicable – 25 copies)
- 7) Informed Consent/Assent Document(s) (if applicable – 25 copies) (**NOTE:** If this is a DHHS protocol, you **MUST** include the DHHS-approved consent/assent documents)
- 8) VCU IRB Children-Subject Form (if applicable – 25 copies)
- 9) VCU IRB Pregnant Women, Fetuses, Neonates-Subject Form (if applicable – 25 copies)
- 10) VCU IRB Prisoner-Subject Form (if applicable – 25 copies)
- 11) Conflict of Interest Disclosure Statement. Submit Conflict of Interest Disclosure Statement AND Disclosure Supplement Form(s) IF any of the investigators answered YES to one of the questions. (signatures are required - 25 copies)
- 12) Principal Investigator CV or Biosketch (4 copies)
- 13) FDA Form 1572 (if applicable – 4 copies)
- 14) IND or IDE Application (if applicable – 4 copies)
- 15) Investigator's Brochure (if applicable – 4 copies)
- 16) Documentation of Level of Risk (if applicable – 4 copies)
- 17) Radiation Safety Committee Approval Letter (if applicable – 4 copies)
- 18) Massey Cancer Center Protocol Review and Monitoring System Approval Letter (if applicable – 4 copies)
- 19) Confirmation of receipt of management plan from Investigational Drug Pharmacy (if applicable – 4 copies)
- 20) Research Funding Proposal (if applicable – 4 copies)
- 21) Medically Responsible Investigator CV or Biosketch (if applicable – 4 copies)
- 22) CV of Doctoral Student, Postdoctoral Scholar, Fellow, or Resident (if applicable – 4 copies)

## VCU RESEARCH PLAN TEMPLATE

Use of this template is required to provide your VCU Research Plan to the IRB. Your responses should be written in terms for the non-scientist to understand. If a detailed research protocol (e.g., sponsor's protocol) exists, you may reference specific sections of that protocol. **NOTE: If that protocol does not address all of the issues outlined in each Section Heading, you must address the remaining issues in this Plan. It is NOT acceptable to reference a research funding proposal.**

**ALL Sections of the Human Subjects Instructions must be completed with the exception of the Section entitled "Special Consent Provisions."** Complete that Section if applicable. When other Sections are not applicable, list the Section Heading and indicate "N/A."

**NOTE: The Research Plan is required with ALL Expedited and Full review submissions and MUST follow the template, and include version number or date, and page numbers.**

### **DO NOT DELETE SECTION HEADINGS OR THE INSTRUCTIONS.**

#### **I. TITLE**

MOBILE PHONE TEXT MESSAGING AS ADJUNCT TO A COMMUNITY-BASED WEIGHT MANAGEMENT PROGRAM

#### **II. RESEARCH PERSONNEL**

##### **A. PRINCIPAL INVESTIGATOR**

List the name of the VCU Principal Investigator

Salyer, Jeanne PhD, RN

##### **B. STUDY PERSONNEL**

NOTE:

1. Information pertaining to each project personnel, including their role, responsibilities, and qualifications, is to be submitted utilizing a *VCU IRB Study Personnel Information and Changes Form*. This form is available at <http://www.research.vcu.edu/forms/vcuirb.htm>.
2. A roster of all project personnel, including the principal investigator, medically responsible investigator, and non-VCU personnel, is to be maintained as a separate study document which is retained with the Research Plan, and is to be updated as necessary. This template document, entitled *VCU IRB Study Personnel Roster*, is available at <http://www.research.vcu.edu/forms/vcuirb.htm>.

**C. Describe the process that you will use to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions.**

The PI will be closely working with the doctoral student throughout the study. They will ensure to review the IRB plan, study forms, inclusion and exclusion criteria, informed consent procedures, data collection procedures and other study documents thoroughly prior to initiation of study.

#### **III. CONFLICT OF INTEREST**

Describe how the principal investigator and sub/co-investigators might benefit from the subject's participation in this project or completion of the project in general. Do not describe (1) academic recognition such as publications or (2) grant or contract based support of VCU salary commensurate with the professional effort required for the conduct of



The researchers will not benefit from subjects participation or completion of this project.

#### IV. RESOURCES

Briefly describe the resources committed to this project including: (1) time available to conduct and complete the research, (2) facilities where you will conduct the research, (3) availability of medical or psychological resources that participants might require as a consequence of the research (if applicable), and (4) financial support.

(1)The student is taking a dissertation credits under the PI's name (9 credits). This project is the student's dissertation. (2) Recruitment, enrollment, demographics and questionnaire completion will be conducted in both campuses: on MCV campus in the MCV Alumni House, room 217 and on Monroe campus in the University Student Commons, Forum room. (3) Dr. Salyer have available the resources of the Center of Excellence for Biobehavioral Approaches to Symptom Management in the Nursing school to assist with building the data base, data entry, data monitoring, data analysis consultation, and preparation of an analysis-ready data set. (4) Infield Health® (www.infieldhealth.com) a professional corporation with a mission to guide patients toward optimal health through mobile technology will support the research study by sending behavioral text messages biweekly to participants free of charge. In addition the Human Resource Department at VCU will provide one session with a personal trainer to one of the participants in each group. The session with a personal trainer will be held in the Recreational Sports Center at VCU. Furthermore, upon enrollment, each participants will receive a \$10.00 store gift card.

#### V. HYPOTHESIS

Briefly state the problem, background, importance of the research, and goals of the proposed project.

The prevalence of overweight and obesity is still on the rise. The latest estimates from the National Health and Nutrition Examination Survey NHANES obtained in 2009 – 2010, revealed that 68% of adults in the United States are either overweight or obese (Flegal et al., 2012). Obesity is associated with increased risk of health co-morbidities like type II diabetes, hypertension, cardiovascular diseases and cancer (Lawrence & Kopelman, (2004) and present a great public health concern by the epidemiological and economic burden placed on the health system (Finkelstein et al., 2009). Research has shown that even a small reduction of 5% – 10% in initial body weight can reduce the obesity related comorbidities (Blackburn, 1995; Pasanisi et al., 2001; Ross & Bradshaw, 2009). Although different modalities exist to treat obesity, lifestyle interventions have been demonstrated to be successful for both short and long-term weight loss in overweight and obese individuals (Galani & Schneider, 2007; Brown, et al., 2009; Goodpaster et al., 2010). In a systematic review of behavioral and cognitive-behavioral interventions for overweight and obesity, the evidence implied that a combination of behavioral treatment of obesity and overweight with diet and exercise appears to result in a greater weight loss than interventions with diet and exercise components alone (Shaw et al., 2005; Spahn et al., 2010). Lifestyle interventions usually consist of a diet and exercise plan, in addition to a behavioral treatment and often include individual counseling in order to promote in overweight and obese individuals the adoption of healthy eating and exercise habits, problem solving and goal setting enabling them to reach a healthy weight (Wadden, 2000). Some of the behavioral components as continuous self-monitoring (Carels et al., 2005) goal setting, problem solving, social support, and adherence to weight loss programs, have shown to be strong predictors of success in weight management (Del Corral, 2011; Spahn et al., 2010). Some of the limitations encountered with standard in person behavioral weight loss interventions are the increased costs of long term interventions, and the burden to researchers and participants related to location and time constraints (Tufano & Karras, 2005). The ubiquitous spread of cellular phones and mobile technology appears to offer an effective clinical alternative to face to face standard interventions with a minimal cost and an advantage of reaching mass population (Pellegrini et al., 2011). In fact, the adoption trend of mobile technology shows constant increase. According to the International Association for the Wireless Telecommunications Industry, as of June 2011, the United States has an estimated 322.9 million wireless subscribers (CTIA, 2011). Mobile phone adoption has been widely disseminated across all socioeconomic and demographic groups, especially in African American and Hispanic population that are in great need for these types of interventions (Flegal et al., 2012). In fact, data shows that 87% of African American and Hispanic adults versus 80% White adults are more likely to have a cell phone “pew research Smith, 2010” and are surpassing White adults by the

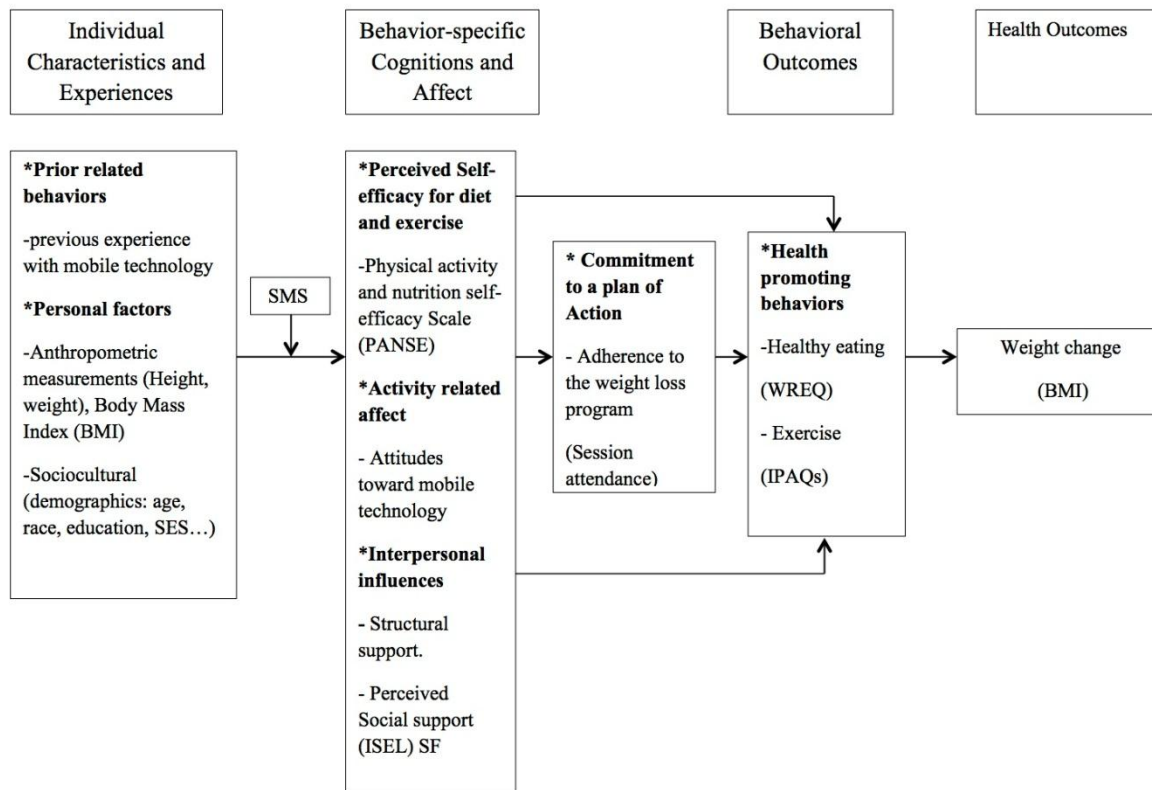
frequency of usage of text messaging. In fact, Short Messaging System (SMS) appears to be the most common non-voice application used on mobile phones. Around 73% of adult mobile phone owners admit using the text messaging function of their mobile phone at least occasionally (Smith, 2011).

Despite encouraging results, little research has explored the utility of SMS in weight management. Thus, our understanding of how SMS can affect behavioral and health outcomes is limited. The goal of this research, therefore, is to contribute to the developing knowledge of how using the SMS may influence relevant outcomes in overweight and obese population in a group setting and provide direction for effective weight management strategies.

### Theoretical Framework

To synchronize the different concept and variables applicable to promoting behavioral change in overweight and obese population, the Health Promotion Model (HPM) will serve as a framework to guide the proposed study (see figure.1).

Figure 1. Proposed Study Framework adapted from The Health Promotion Model (Revised). Pender, Murdaugh & Parsons, 2002.



### Theoretical underpinnings of Health Promotion Model

The Health Promotion Model was created to constitute a framework for integrating nursing and behavioral science perspectives on factors influencing health behaviors. The framework was offered as a guide for exploration of the complex biobehavioral processes that motivate individuals to engage in health enhancing behaviors (Pender, 1982). Health promotion as defined by the World Health Organization (WHO) is the process of enabling people to increase control over, and to improve their overall health (Ottawa, 1986).

The HPM depicts the multidimensional nature of individual interaction with their interpersonal and physical environments as they engage in behaviors to pursue health (Pender et al., 2006). Relationship among individual characteristics and experiences and behavior-specific cognitions and affect are incorporated in the proposed conceptual framework as well as commitment to a plan of action, behavioral and health outcomes.

### ***Individual characteristics and experiences***

Individual characteristics. Individual characteristics are specific and unique for each individual. These personal characteristics constitute a baseline of unchangeable experience from which individuals may engage in health promoting behaviors (Grubbs & Carter, 2002). It includes personal biologic factors like age, weight and BMI and socio-cultural factors such as ethnicity, education and income.

Prior related behaviors. Prior related behaviors as in previous experiences with mobile technology can have both direct and indirect effects on engagement in health promotion behaviors due mainly to habit formation. The frequency of behaviors in the past appears to be the best predictor of healthy behaviors (Shin et al., 2005).

### ***Behavior- Specific Cognitions and Affect***

#### ***Perceived self-efficacy***

Perceived self-efficacy, activity related affect and interpersonal influences are considered essential variables which determine the commitment to health promoting behaviors (Pender et al., 2006). According to HPM, self-efficacy motivates health promoting behaviors directly by efficacy expectations and indirectly by affecting perceived barriers to pursue a plan of action (Pender et al., 2006). Empirical research conducted in the domain of weight management, identified perceived self-efficacy as a strong predictor of weight loss related behaviors (Byrne, 2002; Elfhag & Rossner, 2005).

#### ***Activity related affect***

According to HPM, activity related affect is the act of affective responses associated with the thought of a specific behavior (Pender et al., 2006). A positive affect toward a behavior can result in a higher perceived self-efficacy and a greater commitment to plan of action. Thus, attitudes toward mobile technology will be assessed in participants.

#### ***Interpersonal influences***

#### ***Perceived Social support***

Social support has been identified as central to successful weight loss and maintenance (Elfhag & Rossner, 2005; Fukuoka et al., 2011) and behavior change (Hwang et al., 2012). It is important to differentiate between two main concepts in social support: structural and functional support. Structural support relates to the availability of support and is measured by the frequency, daily or weekly, and administration method, face-to-face interaction, online social networking of social support. In contrary, functional support is more related to the individual perception of the quality of support received. In weight loss interventions, functional support is strongly related to health outcomes (Verheijden et al., 2005). Perceived social support and use of self-regulatory behaviors were found to be strong predictors of physical activity and nutrition behavior (Anderson et al., 2011).

#### ***Commitment to Plan of Action***

According to a HPM, the more an individual work is committed to a plan of action, the more likely is the long-term maintenance of health promoting behaviors (Pender et al., 2006). A commitment to a plan of action can be tested in the adherence to a weight-loss program that an individual is enrolled in. In weight management interventions, higher rate of adherence to weight interventions was correlated with higher percentage of weight loss (Burke et al., 2010; Patrick et al., 2009; Haapala et al., 2009).

### ***Behavioral and health outcomes***

The HPM proposes that health promoting behaviors are eventually directed toward achievement of positive health outcomes (Pender et al., 2006). When individuals adopt healthy behaviors into their lifestyle, their overall health will be improved and achieve a better quality of life. Healthy eating and regular exercise are considered the cornerstone for attaining a healthy weight and maintain it over time (Barnard & Roberts, 2005; Dubnov et al., 2003; Galani & Schneider, 2007).

## **VI. SPECIFIC AIMS**

1. The first aim of the study is to assess the utility of two features of the mobile phone SMS (tailored messages as a type of social support) on change in behavioral and health outcomes in an experimental versus a control group of overweight and obese participants in a structured weight management program. It is hypothesized that tailored text messaging will:
  - i. promote healthy eating behaviors.

- ii. Increase time spent in physical activity per week.
- iii. Increase the perceived self-efficacy for nutrition and physical activity.
- iv. Enhance participants' adherence to the weight loss program.
- v. Increase their perception of social support available for participants in order to reach their healthy weight.
- vi. Lead to a greater acceptance of mobile technology.
- vii. Lead to a decrease in BMI.

The second aim of this study is to explore which demographics/individual characteristics variables predict behavior specific cognitions and affect. Potential predictors are demographic/personal factors (i.e. previous experience with mobile technology, BMI, age, education);

It is hypothesized that:

- i. a previous experience with mobile technology, will predict a higher acceptance of mobile technology.
- ii. There is a negative relationship between BMI and perceived self-efficacy for diet and exercise and perceived social support. A higher BMI will predict a poor self-efficacy and a lower perception of social support.
- iii. A higher education and socioeconomic class will increase perceived self-efficacy for diet and exercise and social support.

3. The third aim of this study is to reach a better understanding of the text messaging acceptability and utility among participants in a group setting and identification of areas of intervention that needs improvement. Thus, measures of utility and acceptability will be included in the evaluation of the intervention.

## VII. BACKGROUND AND SIGNIFICANCE

Include information regarding pre-clinical and early human studies. Attach appropriate citations.

Text messaging has the advantage to instantly reach individuals and is accessed at their own convenience and comfort, at a low cost compared to other mediums such as phone calls (Chen et al., 2008). The ubiquitous spread of mobile phone technology and text messaging makes it an ideal medium to reach a large scale population. The utility of text messaging has been tested across different preventive health behavior interventions (Fukuoka et al., 2011). For instance, text messaging was used as a reminder to improve patients' attendance in outpatient clinics (Downer et al., 2006; da Costa a, 2010; Koshy et al., 2008) as adjunct to smoking cessation interventions (Snider et al., 2011; Free et al., 2011) to improve asthma control (Prabhakaran et al., 2010) and diabetes management (Ferrer et al., 2004). Findings suggest that SMS can be an efficient medium to provide patient education, reminders, behavioral interventions, data acquisition and two-way communications between individuals and healthcare providers (Chen et al., 2008; Krishna et al., 2009). A systematic review of behavioral change interventions using the mobile phone text messaging feature identified positive behavior change outcomes in 13 out of the 14 reviewed studies (Fjeldsoe et al., 2009). Some of the important features that correlated with behavioral changes in SMS delivered intervention were tailored text messages to fit individual needs, interactivity between health providers and individuals, intervention initiation and dialogue by either the researcher or participant. Krishna et al. (2009) conducted a systematic review evaluating cell phone voice and text messaging interventions in 25 interventions. Findings from the review suggested that activity related to healthcare delivery and clinical improvements were greatly improved by information and education interventions delivered via mobile technology. Chronic health conditions benefited the most from advice and support delivered through mobile phones. The use of text messages has been found to be higher among young population as compared to older adults, and minimized the digital disparity across gender and race (Krishna et al., 2009; Denizard et al., 2011). The frequency of SMS delivery was not consistent across studies and ranged from frequent daily messages (Tasker et al., 2007; Bramley et al., 2005) to once a week (Vidrine et al., 2006; Kim & Son, 2008). Another research study surveyed consumers on their views of delivering of a weight-loss intervention via mobile phone. Participants were supportive of using mobile phone as a medium to deliver weight-loss interventions and highlighted the need for interventions to be tailored toward individual needs (Gorton et al., 2011). The use of text messaging alone or as an adjunct to health behavioral interventions for weight management in overweight or obese adults is still very limited despite some research studies showing encouraging results.

Haapala et al. (2009) randomized participants to experimental group using a mobile phone application, and a control group who did not receive any intervention. The Weight Balance® application was delivered through SMS to the experimental group and relied on participants' response to deliver tailored text messages. The weight management program calculated participants' daily energy requirement and encouraged them to reduce their food intake, increase their physical activity and weighing daily. Participants were also permitted to set their short and long-term weight goals. Dietary habits, frequency of

physical activity and self-efficacy in dieting were assessed at baseline, 6 and 12 months. At 12 months, there was a significant weight loss of 1.3 kg in the experimental group compared to the control group ( $p = 0.006$ ).

Joo and Kim (2007) relied on the SMS feature of mobile phones to deliver a behavioral treatment for obesity. 463 participants received a weekly SMS related to behavioral modification along with a brochure on exercise and diet sent by mail. They were encouraged through text messaging to reduce their calorie intake by 500 calories per day and increase their physical activity to 30 minutes per day for more than four times per week. After 12 weeks, participants exhibited a significant reduction in body weight (1.5 kg) and BMI (0.6 kg/m<sup>2</sup>).

Patrick et al. (2009) randomized 78 participants into a control group receiving monthly printed materials regarding weight loss and an experimental group receiving personalized SMS and Multimedia Message Service MMS 2 to 5 times daily, in addition to printed materials and brief monthly phone call from a counselor. The tailoring in the SMS included frequency and time preference to message delivery. The topic of messages was changed weekly and included behavioral, diet and physical activity from components. Assessment was done at baseline, 2 and 4 months. At 4 months, the intervention group lost more weight, an average of 5 kg, than the comparison group who did not achieve any weight loss ( $p = 0.02$ ). 92% of participants reported satisfaction with the technology.

Lee et al. (2011) used a quasi-experimental intervention to deliver a self-management intervention including healthy diet and exercise relying on weekly SMS and monthly phone counseling on weight management. The control group received a structured exercise program consisting of a three 1 hour walking class per week. All participants were assessed at baseline and at 12 weeks. The attrition rate in both groups was higher than 50%. At the end of the intervention, both groups had a decrease in BMI but there was no significant difference in bodyweight between the two groups.

McGraw K. (2010) explored the effect of persuasive motivational text messaging on adherence to diet and exercise across different personality traits. All participants were asked to record their food intake, exercise, stress, motivation and weekly weight. The experimental group received motivational SMS; the control group did not receive any intervention. The participants were assessed at baseline and after 5 weeks. There was no significant difference in BMI changes between groups. In addition different traits of personality did not predict weight change.

In conclusion, research has shown that tailored interventions may improve the effectiveness of weight loss interventions and adoption of healthy behaviors. Despite the positive findings, the evidence base cannot be concluded. Most of the studies did not use the text messaging features as a stand-alone intervention but was often used in adjunct to another behavioral intervention, which makes it difficult to evaluate the true effect of the intervention. The proposed study will address these gaps in knowledge regarding the utility of text messaging as a stand-alone intervention and further explore the effects of text messaging on behavioral and health outcomes.

#### VIII. PRELIMINARY PROGRESS/DATA REPORT

If available.

N/A

#### IX. RESEARCH METHOD AND DESIGN

Include a brief description of the project design including the setting in which the research will be conducted and procedures. If applicable, include a description of procedures being performed already for diagnostic or treatment purposes.

##### Study Design

The proposed experimental study aims to explore the effect of text messaging, as an adjunct to a community-based weight loss program, on behavioral and health outcomes. Controlling for the effect of a structured at work weight loss program offered by Weight Watchers, the researchers are focusing on isolating the effect of text messaging on behavioral change in eating and physical activity, commitment to the weight-loss program, and ultimately body weight change. Participants will not be randomized but they will be assigned to a control and experimental group. The reason for assignment is to keep homogeneity among each group, and to preserve the familiarity and social support in each cohort group. The study period is for 12 weeks and will take place at VCU on MCV and Monroe campuses. Participants on Monroe campus will be the control group, and participants at MCV campus will be the experimental group receiving the text message intervention. The intervention will be conducted through the online text messaging system TextJab®. The latter is a commercially

available service from Infield Health Company which promotes optimal health in individuals through usage of mobile technology. TextJab® works by sending text messages promoting healthy behaviors and expect receiving an answer from participants upon completion of the requested behaviors (e.g try to drink 8 glasses of water today and tomorrow). Messages will be selected from a pool of comments provided by participants at recruitment. For instance, participants will be asked to list their three perceived main barriers for reaching a healthy weight. Afterward the researchers will tailor the content of the text messages to respond with a doable behavioral answer to the perceived barriers. Tailored text messages are more likely to address individual needs and to promote adoption of healthy behaviors. Text messages will be sent to participants mobile phones in the experimental group two times per week over a period of 12 weeks. The system also includes online access to the website (www.infieldhealth.com) where participants can have access to a dashboard to track individual progress. The difference between groups regarding behavioral and health outcomes would be assessed at baseline and at 12 weeks.

#### Setting and recruitment

Recruitment will take place in the Weight Watchers place of weekly meeting which is the University Student Commons, forum room on Monroe campus and the MCV alumni house, room # 217 on MCV campus. The primary investigator and the student will attend the Weight Watchers meetings at MCV and Monroe campus and introduce themselves and explain verbally the purpose of the study to the participants. Interested participants will be met afterward to answer any further questions and to complete the enrollment process.

#### Sample size

The proposed study is a pilot research. Researchers are hoping for a recruitment of 10 - 15 participants per group. If for any reason this number could not be met, researchers will proceed with the enrolled available participants. Researchers are hoping to recruit during the last meeting of the ongoing current session on Monroe campus which will end on May 28, and at the meeting of the first week of the following new session which will begin on June 4, 2012. On MCV campus, researchers are hoping to recruit during the last meeting of the ongoing current session which will end on June 6, and at the meeting of the first week of the following new session which will begin on June 13, 2012.

#### Inclusion and exclusion criteria

The inclusion criteria are:

1. 18 years and older.
2. Healthy overweight or obese adults with a BMI between 25- 39.9 kg/m<sup>2</sup>.
3. If female, not to be pregnant or planning on becoming pregnant in the coming 6 months.
4. Enrolled in a weight loss with the Weight Watchers at-work program at Virginia Commonwealth University and not a maintenance program.
5. Own a mobile phone device enabling the receiving and sending of text messages.

The exclusion criteria are:

1. Participants do not own a cellular phone with the text messaging feature.
2. Pregnant women or planning on becoming pregnant in the coming 6 months.
3. Morbidly obese participants with a BMI  $\geq 40$  kg/m<sup>2</sup>.

The reason for these exclusions relate to the fact that even though participants in the control group will not receive any SMS messages, nevertheless they are required to have a mobile phone enabling text messages, in order to be compared with intervention group participants.

As for pregnant women they are excluded from the study since pregnancy is coupled with weight gain rather than weight loss. In addition, the National Institute for Health and Clinical Excellence (NICE, 2006) classifies participants with a BMI above the cut off of  $\leq 39.9$  kg/m<sup>2</sup> as morbidly obese. Obesity guidelines recommend bariatric surgery as a treatment option for subjects with a BMI of 40 kg/m<sup>2</sup> or more since morbid obesity is associated with health comorbidities and high risk of death. Participants below the cut off of a BMI of 25 kg/m<sup>2</sup> are considered to have a healthy weight and do not need to lose weight but maintain it (NICE, 2006).

#### Data collection

Upon enrollment and after signing the consent form, researchers will measure the height and weight of each participant, and give each one a paper and pencil questionnaire packet to complete. Measurements, with the exception of height and demographics will be taken at baseline and at 12 weeks. Please refer to appendix D for the list and details of the study measures.

#### Variables and outcomes measures

Please refer to appendix D for all the list of questionnaires and scales.

*Anthropometric Measures and health outcome*

Change of body weight. A change of body weight is the health outcome of interest. The body measurements will be performed by the doctoral student. Body height will be measured using a wall mounted stadiometer and height will be recorded in centimeters. A calibrated electronic digital floor scale Weight Watchers will be used to measure body weight in pounds and then converted to kilogram by dividing the total weight in pounds by 2.2. The measures of height and weight will be used to calculate BMI (weight in kg / [height] m<sup>2</sup>). The measurement of weight (health outcome) will be taken in the experimental and control group at baseline and at 12 weeks and BMI will be calculated accordingly.

#### **Sociocultural and demographics information**

Participants will be answering a demographic questionnaire with information such as gender, age, education, etc... After completion of the questionnaire, participants will be asked to list three main barriers which are interfering with reaching their healthy weight. Answers will be then used by researchers to create a list of tailored text messages to be sent to individuals in the experimental group.

#### *Previous experience in mobile technology*

Previous experience with technology will be assessed objectively in participants by answering general questions regarding the frequency and the features most used in their mobile phone.

#### **Behaviors specific cognitions and affect**

##### *Perceived self-efficacy*

Perceived self-efficacy will be measured using the Physical Activity and Nutrition Self-Efficacy PANSE scale (Latimer et al., 2011). The PANSE scale includes 11 items and was developed to effectively assess self-efficacy for both nutrition and physical activity, so that researchers might use one brief instrument for weight loss behaviors. Participants can rate their response on a scale from 1 to 5 ranging from “not at all” to “completely confident”. The PANSE scale demonstrated a test-retest reliability scores of  $r = 0.55$ ,  $p < .01$  with Cronbach  $\alpha$  of  $r = 0.89$  (Latimer et al., 2011). Perceived self-efficacy will be measured in both groups at baseline and at 12 weeks.

##### *Attitudes toward technology*

Attitudes toward technology will be measured using questions adapted from the Technology Acceptance Model developed by Davis (1986). Three major concepts will be measured: the perceived usefulness related to how much the individual sees the technology being useful, the perceived ease of use related to how much the technology is easy to use, and the adoption intention which relates to the behavioral intention of the individual to use that technology. Participants will answer five items questionnaire with answers ranging from strongly disagree to strongly agree. Measurements will be taken at baseline and at 12 weeks.

##### *Perceived social support*

The Interpersonal Support Evaluation List ISEL subscale will be used to measure the perceived social support in participants in both groups (Cohen 1985). Short Form consists of a list of 16 statements concerning the perceived availability of potential social resources. The general ISEL is designed to identify the availability of support along four dimensions: tangible aid, appraisal, self-esteem, and belonging. The test retest reliability score of  $r = 0.88$  and a coefficient  $\alpha = 0.90$ . Perceived social support will be measured in both groups at baseline and at 12 weeks.

#### **Commitment to a plan of action**

Commitment to a plan of action will be characterized as the number of meetings attended during the 12-week program. Adherence to the weight loss program will be objectively measured by calculating the number of attendance to the Weight Watchers weekly sessions. Attendance books will be reviewed at 12 weeks in both groups.

#### **Behavioral outcomes**

##### *Eating behaviors*

Eating behaviors will be assessed using the Weight-Related Eating Questionnaire WREQ (Schembre & Geller, 2011). The WREQ consist of 16-items related to weight and assesses theory-based aspects of eating behavior across different population. All the WREQ subscales had high reliability coefficients suggesting good test-retest reliability  $r = 0.74 - 0.93$  (Schembre & Geller, 2011). Validity analyses supported the four subscales characteristics related to eating behavior. WREQ will be administered in both groups at baseline and at 12 weeks.

##### *Exercise*

Physical activity will be measured by The International Physical Activity Questionnaires IPAQ. The purpose of the IPAQ is to obtain internationally comparable data on health-related physical activity. The IPAQ was originally developed in Geneva in 1998 and its short form was recommended for administration in population monitoring (Craig et al., 2003). Reliability and validity was tested extensively across 12 countries in addition, previous research showed criterion validity Spearman correlations with a median of 0.30 and test-retest reliability Spearman correlations  $r = 0.8$  (Craig et al., 2003; Bassett, 2003).

The IPAQ consists of seven questions and inquires about time spent being physically active in the last 7 days. Participants in both groups will answer the questionnaire at baseline and at 12 weeks.

Evaluation of the intervention

At the end of the intervention, the participants in the experimental group will be asked four questions to assess their perceived usefulness of the intervention.

#### X. PLAN FOR CONTROL OF INVESTIGATIONAL DRUGS, BIOLOGICS, AND DEVICES.

Investigational drugs and biologics: IF Investigational Drug Pharmacy Service (IDS) is not being used, attach the IDS confirmation of receipt of the management plan.

Investigational and humanitarian use devices (HUDs): Describe your plans for the control of investigational devices and HUDs including:

- (1) how you will maintain records of the product's delivery to the trial site, the inventory at the site, the use by each subject, and the return to the sponsor or alternative disposition of unused product(s);
- (2) plan for storing the investigational product(s)/ HUD as specified by the sponsor (if any) and in accordance with applicable regulatory requirements;
- (3) plan for ensuring that the investigational product(s)/HUDs are used only in accordance with the approved protocol; and
- (4) how you will ensure that each subject understands the correct use of the investigational product(s)/HUDs (if applicable) and check that each subject is following the instructions properly (on an ongoing basis).

N/A

#### XI. DATA ANALYSIS PLAN

For investigator-initiated studies.

All data collection forms will be sent to the Data Manager and entered into a MS Access data base where it will be cleaned for accuracy. The Data Manager will continuously monitor data security and quality. Next, data from MS Access will be uploaded into an SPSS (v.17) data file (SPSS, Inc., Chicago, IL). One of the first steps in building the data base will be to compute continuous scores characterizing each of the prior related behaviors, behavior specific cognitions and affects, behavioral and health outcomes. For each multi-item measurement scale, the physical activity and nutrition self-efficacy scale, PANSE, attitudes toward mobile technology, previous experience with mobile technology social support questionnaire, The Interpersonal Support Evaluation List (ISEL) for social support, the weights related eating questionnaire (WREQ), the international physical activity questionnaire (IPAQ), a summary score will be computed for use in data analysis.

##### *Descriptive Statistics*

Descriptive statistics will be obtained as well as numbers to describe the sample including calculating means, standard deviations, and ranges for the continuous variables, and counts with frequencies for the categorical variables. An analysis of variance test ANOVA or independent samples t-test will be used to examine any differences between group assignments or differences at baseline. An intention to treat analysis (ITT) will be conducted to carry baseline data forward for any missing values. Participants with missing follow-up data on the outcome variables of interest will be excluded from the analysis. Group differences will be examined by 2 x 2 mixed ANOVA (group by time). In case data will not be normally distributed, a nonparametric test (Kruskal-Wallis) will be performed. A one-way ANOVA or independent samples t-tests will examine the difference in proposed measures between groups among completers. A Pearson correlational analysis will be performed to examine the relationship between proposed measures and change in eating behaviors, physical activity behaviors and body weight change at 12 weeks. The effect of the SMS on adherence to the weight management program will be assessed using a 2-tailed test. The number of meeting session attended will be calculated using the mean with the standard deviation. Statistical significance is defined at  $p < 0.05$ .



## XII. DATA AND SAFETY MONITORING

- If the research involves greater than minimal risk and there is no provision made for data and safety monitoring by any sponsor, include a data and safety-monitoring plan that is suitable for the level of risk to be faced by subjects and the nature of the research involved.
- If the research involves greater than minimal risk, and there is a provision made for data and safety monitoring by any sponsor, describe the sponsor's plan.
- If you are serving as a Sponsor-Investigator, identify the Contract Research Organization (CRO) that you will be using and describe the provisions made for data and safety monitoring by the CRO. Guidance on additional requirements for Sponsor-Investigators is available at <http://www.research.vcu.edu/irb/wpp/flash/X-2.htm>

The pilot study is an experimental controlled behavioral research, not a clinical trial, that will be overseen by the PI. We believe that the protocol constitute a minimal risk to participants. The PI and/or the student will be available 24 hours a day by cell phone whenever subjects are on project; this number will be provided to subjects.

The student will manage data under the PI's supervision. Initial contact and invitation to participate in the study and informed consent will be conducted by the student or Dr. Salyer. Participants will complete questionnaires, anthropometric measures and demographic data in the same day. All completed information will be hand-delivered to the Center data manager and placed in a locked file cabinet prior to data entry.

The study will follow general procedures of the Center of Excellence for Biobehavioral Approaches to Symptom Management at the School of Nursing. All data will be housed on a secure server with restricted access. Data stored in the Infield Health corporation will contain only the phone number of participants in the experimental group and their response when they receive the behavioral health message (yes or no). Phone number is required in order to be able to send text messages to participants. Infield Health data will be stored in a secure database with restricted access, requiring identification and password access. The PI and student will be provided with a secure code and a password in order to access the data on the company secure server. At the time of enrollment, each study participant will be assigned a unique identifier by the PI. No individual names will be linked with the data. These unique identifiers and associated participant names will be kept in a locked file in the PI's office. Center staff and the PI will monitor and report all adverse events to the VCU IRB and, as appropriate, to the study participants. The Center's data manager will store the completed questionnaires in a locked cabinet in the Center offices; data quality will be monitored by the data manager in consultation with the PI. Questionnaires are then transferred to electronic database. Data entry will be an ongoing process and entry will occur generally within a week of data collection. The data manager will regularly monitor for out-of-range values or logical inconsistencies. A double-check system will be used for accuracy and consistency of coding and data entry. Data are entered directly on to a secure server with secure back-up. The computer database system and files will be maintained by experienced personnel. An analysis-ready data file, with participants identified only by assigned code numbers, will be provided (electronically) to the PI upon completion of data collection.

Planned study involves minimal risk; no adverse events are expected to occur as a direct result of subject participation. However, should any event occur that might be related to project participation, the PI will assume responsibility for notification of the designated care providers and for any referral for recommended treatment, as well as notification to the VCU IRB. Adverse event reporting forms and procedures are available on-line at: <http://www.orsp.vcu.edu/irb>

## XIII. MULTI-CENTER STUDIES

**If VCU is the lead site in a multi-center project or the VCU PI is the lead investigator in a multi-center project, describe the plan for management of information that may be relevant to the protection of subjects, such as reporting of unexpected problems, project modifications, and interim results.**

N/A

## XIV. INVOLVEMENT OF NON-VCU INSTITUTIONS/SITES (DOMESTIC AND FOREIGN)

**1. Provide the following information for each non-VCU institution/site (domestic and foreign) that has agreed to participate:**

- Name of institution/site

IRB USE - Do Not Delete

- Contact information for institution/site
- Engaged in Research or not (if YES AND the research involves a DIRECT FEDERAL AWARD made to VCU, include FWA #). See OHRP’s guidance on “Engagement of Institutions in Research” at <http://www.hhs.gov/ohrp/policy/engage08.html>.
- Request for the VCU IRB to review on behalf of the Non-VCU institution? See requirements found at <http://www.research.vcu.edu/irb/wpp/flash/XVII-6.htm>.
- See VCU WPPs:  
<http://www.research.vcu.edu/irb/wpp/flash/XVII-6.htm> and  
<http://www.research.vcu.edu/irb/wpp/flash/XVII-11.htm>.

Name of Institution	Contact Information for Site	Engaged (Y/N) and FWA # if applicable	Request for VCU IRB to review on behalf of the non-VCU institution (Y/N)*

\*NOTE: If a Non-VCU site is engaged in the research, the site is obligated to obtain IRB review or request that the VCU IRB review on its behalf.

2. Provide a description of each institution’s role (whether engaged or not) in the research, adequacy of the facility (in order to ensure participant safety in the case of an unanticipated emergency), responsibilities of its agents/employees, and oversight that you will be providing in order to ensure adequate and ongoing protection of the human subjects. You should only identify institutions that have agreed to participate. If additional institutions agree to participate at a later time, they must be added by amendment to the protocol.

N/A

XV. HUMAN SUBJECTS INSTRUCTIONS

ALL sections of the Human Subjects Instructions must be completed with the exception of the section entitled “Special Consent Provisions.” Complete that section if applicable.

A. DESCRIPTION

Provide a detailed description of the proposed involvement of human subjects or their private identifiable data.

The proposed involvement of participants will include a total time commitment of approximately one hour at the enrollment and one hour at the end of the study. During this time eligible participants who are willing to participate in the study will sign the consent form, complete a demographic survey and be asked to complete the designed questionnaires. Their height and weight will be measured and recorded as well.

B. SUBJECT POPULATION

Describe the subject population in terms of sex, race, ethnicity, age, etc., and your access to the population that will allow recruitment of the necessary number of participants. Identify the criteria for inclusion or exclusion of all targeted populations and include a justification for any exclusions. Explain the rationale for the involvement of special cases of subjects, such as children, pregnant women, human fetuses, neonates, prisoners or others who are likely to be vulnerable. If you plan to allow for the enrollment of Wards of the State (or any other agency, institution, or entity), you must specifically request their inclusion and follow guidance in VCU IRB WPP XV-3: Wards and Emancipated Minors available at <http://www.research.vcu.edu/irb/wpp/flash/XV-3.htm>.



The population will include overweight or obese male and female participants currently enrolled in the Weight Watchers at work wellness program at VCU, 18 years and older from various ethnicities, and race. Participants should have a Body Mass Index (BMI) of  $\geq 25$  kg/m<sup>2</sup> and  $\leq 39.9$  kg/m<sup>2</sup> and own a mobile phone device allowing them to send and receive text messaging. Pregnant women will be excluded from the study since pregnancy is coupled with weight gain rather than weight loss. In addition, participants below the cut off of a BMI of 25 kg/m<sup>2</sup> are considered to have a healthy weight and do not need to lose weight but maintain it. Also participants with a BMI above the cut off of  $\leq 39.9$  kg/m<sup>2</sup> are considered to be morbidly obese

### C. RESEARCH MATERIAL

Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

The research material that will be obtained and recorded will consist of participant-reported questionnaire data. No one other than the investigators will have access to the data. All data will be obtained only for research purposes.

### D. RECRUITMENT PLAN

Describe in detail your plans for the recruitment of subjects including:

- (1) how potential subjects will be identified (e.g., school personnel, health care professionals, etc),
- (2) how you will get the names and contact information for potential subjects, and
- (3) who will make initial contact with these individuals (if relevant) and how that contact will be done.

If you plan to involve special cases of subjects, such as children, pregnant women, human fetuses, neonates, prisoners or others who are likely to be vulnerable, describe any special recruitment procedures for these populations.

The student and the PI will attend sessions of the Weight watchers meetings at both campuses, introduce themselves and verbally explain the purpose of the study. Interested participants will be seeing privately to determine if they meet inclusion criteria and have further questions regarding the study. When eligible participants agreed to enroll in the study, the informed consent will be presented for them to sign and enrollment will be completed by study personnel (PI, student).

### E. PRIVACY OF PARTICIPANTS

**NOTE: Privacy refers to individuals and their interests in controlling access to their identities, their physical person, and how and what kind of information is obtained about them. Privacy also encompasses the interests of defined communities (e.g. those with a certain diagnosis or social circumstance) in controlling access to the group identity and information about the group or individuals as part of the group.**

Describe how the privacy interests of subjects (and communities, if appropriate) will be protected including:

- (1) in the research setting (e.g., in the identification, recruitment, and intervention settings) and
- (2) with the information being sought and the way it is sought. For example, providing drapes or barriers, interviewing in a private room, and collecting only the amount of sensitive information needed for identification, recruitment, or the conduct of the study.

Participants' identities will be protected. Each record will be assigned a code number by the researcher and then identifiable information will be removed from the data record and attached to the consent form. Data stored in the Infield Health corporation will contain only the phone number of participants in the experimental group and their response when they receive the behavioral health message (yes or no). Phone number is required in order to be able to send text messages to participants. Data will be stored in a secure database with restricted access, requiring identification and password access. Consent, demographics and questionnaire will be kept in a locked file in the PI office, accessible only to researchers. All the study visits are conducted in a private room to ensure the participants' privacy.

### F. CONFIDENTIALITY OF DATA

**NOTE: Confidentiality refers to the way private, identifiable information about a subject or defined community is**

**Check all of the following precautions that will be used to maintain the confidentiality of identifiable information:**

- Paper-based records will be kept in secure location and only accessed by authorized study personnel
- Electronic records will be made available only to those personnel in the study through the use of access controls and encryption
- Identifiers will be removed from study-related data (data is coded with a key stored in a separate secure location)
- For research involving web-based surveys, data is secured via passwords and encryption
- Audio or video recordings of subjects will be transcribed and then destroyed to prevent audio or visual identification. Note the date of destruction (e.g., 3 months from close of study; after transcription is determined to be error free).
- Obtaining a Certificate of Confidentiality
- Other precautions:

**G. POTENTIAL RISKS**

**Describe potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.**

Potential risks include mild distress from completing the questionnaire packet. There may be some unpleasant memories that may be brought back from filling out the surveys. The student will explain to the participants that they have a choice of not answering certain questions if they do not wish to do so. However, the likelihood of experiencing mild distress is minimal.

Breach of confidentiality and invasion of privacy is a potential risk. However, all systems and procedures are in place to avoid it from happening. The student will explain that their information is securely stored, will be de-identified and will have restricted access.

**H. RISK REDUCTION**

**Describe procedures for protecting against or minimizing potential risk. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse events to the subjects. Describe the provisions for monitoring the data collected to ensure the safety of subjects, if any.**

As part of the process involved in obtaining written informed consent, participants will be explained and given a copy of the informed consent form along with a description of the study attached to the consent form. Contact information for the PI and the student are provided on the consent form for the participants to ask questions freely. Confidentiality is assured before and throughout the study period. All forms and materials will be stored in a locked cabinet in a locked room and labeled with numbers only. These numbers will be used to enter data into an electronic format. Only the identification numbers will be linked with all forms and materials. For tracking purposes, the participant's phone number will be linked to the questionnaire's identification number but stored separately from all data. Participant names will be stored separately and the potential link to individual names to the forms and materials will be shredded upon completion of the data collection phase. All information will be reported as group information. All information will be analyzed and presented as group information. Individual answers will not be identified.

**I. ADDITIONAL SAFEGUARDS FOR VULNERABLE PARTICIPANTS**

**Describe any additional safeguards to protect the rights and welfare of participants if you plan to involve special cases of subjects such as children, pregnant women, human fetuses, neonates, prisoners or others who are likely to be vulnerable.**

**Safeguards to protect the rights and welfare of participants might relate to Inclusion/Exclusion Criteria: ("Adults with moderate to severe cognitive impairment will be excluded." "Children must have diabetes. No normal controls who are children will be used.") Consent: ("Participants must have an adult care giver who agrees to the participant taking part in the research and will make sure the participant complies with research procedures." "Adults must be**

able to assent. Any dissent by the participant will end the research procedures.”) Benefit: (“Individuals who have not shown benefit to this type of drug in the past will be excluded.”).

N/A

#### J. RISK/BENEFIT

Discuss why the risks to participants are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result. If a test article (investigational new drug, device, or biologic) is involved, name the test article and supply the FDA approval letter.

There are no direct benefits to the subjects in this study as we are seeking information to evaluate the effect of text messaging on behavioral changes in overweight and obese participants in a group setting. It is possible that participants in this project will gain indirect benefits from the knowledge that they are participating in a research project and become aware the importance of adopting healthy behaviors choices in order to achieve optimal health. The risk is minimal and this information may benefit individuals in the future. In addition, the findings of the current study may have future benefits for other participants enrolling in a weight loss program.

#### K. COMPENSATION PLAN

Compensation for participants (if applicable) should be described, including possible total compensation, pro-rating, any proposed bonus, and any proposed reductions or penalties for not completing the project.

Participants in control and experimental group will receive upon enrollment a \$ 10 gift card. Upon completion of the study participants in the control group will be eligible to a drawing prize of a session with a personal trainer provided by the Recreation Sports center at VCU. The same session with the personal trainer will be offered to one participant in the experimental group who will be having the highest record of completion of the behavioral health challenges .There is no penalty for not completing the project.

#### L. CONSENT ISSUES

##### 1. CONSENT PROCESS

Indicate who will be asked to provide consent/assent, who will obtain consent/assent, what language (e.g., English, Spanish) will be used by those obtaining consent/assent, where and when will consent/assent be obtained, what steps will be taken to minimize the possibility of coercion or undue influence, and how much time will subjects be afforded to make a decision to participate.

Investigators will obtain informed consent in a private setting. Study personnel (PI and student) will meet the participants in both campuses before or after the time of a scheduled Weight Watchers meeting. The study will be explained, and researchers will meet with potential participants in a private room to have questions answered and written consent obtained. Participants will be encouraged to take as much time as needed to read or discuss the consent with the investigator, family or friends before making a decision.

##### 2. SPECIAL CONSENT PROVISIONS

If some or all subjects will be cognitively impaired, or have language/hearing difficulties, describe how capacity for consent will be determined. Consider using the VCU Informed Consent Evaluation Instrument available at <http://www.research.vcu.edu/irb/guidance.htm>. If you anticipate the need to obtain informed consent from legally authorized representatives (LARs), please describe how you will identify an appropriate representative and ensure that their consent is obtained. Guidance on LAR is available at <http://www.research.vcu.edu/irb/wpp/flash/XI-3.htm>.

N/A

**3. ASSENT PROCESS**

If applicable, explain the Assent Process for children or decisionally impaired subjects. Describe the procedures, if any, for re-consenting children upon attainment of adulthood. Describe procedures, if any, for consenting subjects who are no longer decisionally impaired. Guidance is available at <http://www.research.vcu.edu/irb/wpp/flash/XV-2.htm> and <http://www.research.vcu.edu/irb/wpp/flash/XVII-7.htm>.

N/A

**4. REQUESTS FOR WAIVERS OF CONSENT (COMPLETE IF REQUESTING ANY TYPE OF WAIVER OF CONSENT OR ASSENT)**

**4-A. REQUEST TO WAIVE SOME OR ALL ELEMENTS OF INFORMED CONSENT FROM SUBJECTS OR PERMISSION FROM PARENTS:** A waiver of informed consent means that the IRB is not requiring the investigator to obtain informed consent OR the IRB approves a consent form that does not include or alters some/all of the required elements of consent. Guidance is available at <http://www.research.vcu.edu/irb/wpp/flash/XI-1.htm>. **NOTE:** Waiver is not allowed for FDA-regulated research unless it meets FDA requirements for Waiver of Consent for Emergency Research (see below).

**4-A.1. Explain why a waiver or alteration of informed consent is being requested.**

**4-A.2. Describe how this study meets ALL FOUR of the following conditions for a waiver or alteration:**

- The research involves no more than minimal risk to the participants. → Explain how your study meets this criteria:
- The waiver or alteration will not adversely affect the rights and welfare of participants. → Explain how your study meets this criteria:
- The research could not practicably be carried out without the waiver or alteration. → Explain how your study meets this criteria:
- Will participants be provided with additional pertinent information after participation?  
 Yes  
 No → Explain why not:

**4-B. REQUEST TO WAIVE DOCUMENTATION OF CONSENT:** A waiver of documentation occurs when the consent process occurs but participants are not required to sign the consent form. Guidance is available at [http://www.research.vcu.edu/irb/wpp/flash/wpp\\_guide.htm#XI-2.htm](http://www.research.vcu.edu/irb/wpp/flash/wpp_guide.htm#XI-2.htm). One of the following two conditions must be met to allow for consenting without signed documentation. Choose which condition is applicable and explain why (explanation required):

The only record linking the participant and the research would be the informed consent form. The principal risk to the participant is the potential harm resulting from a breach of confidentiality. Each participant will be asked whether he/she wants documentation linking the participant with the research and the participants wishes will govern. → Explain how your study fits into the category:

The research presents no more than minimal risk of harm to participants & involves no procedures for which signed

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consent is normally required outside of the research context. → Explain how your study fits into the category:

**4-C. REQUEST TO WAIVE SOME OR ALL ELEMENTS OF ASSENT FROM CHILDREN  $\geq$  AGE 7 OR FROM DECISIONALLY IMPAIRED INDIVIDUALS:** A waiver of assent means that the IRB is not requiring the investigator to obtain assent OR the IRB approves an assent form that does not include some/all of the required elements. Guidance is available at <http://www.research.vcu.edu/irb/wpp/flash/XV-2.htm>.

**4-C.1. Explain why a waiver or alteration of informed consent is being requested.**

**In order for the IRB to approve a request for waiver of assent, the conditions for 4-C.2, 4-C.3, OR 4-C.4 must be met. Check which ONE applies and explain all required justifications.**

**4-C.2.  Some or all of the individuals age 7 or higher will not be capable of providing assent based on their developmental status or impact of illness. → Explain how your study meets this criteria:**

**4-C.3.  The research holds out a prospect of direct benefit not available outside of the research. → Explain how your study meets this criteria:**

**4-C.4.  Describe how this study meets ALL FOUR of the following conditions:**

- The research involves no more than minimal risk to the participants. → Explain how your study meets this criteria:
- The waiver or alteration will not adversely affect the rights and welfare of participants. → Explain how your study meets this criteria:
- The research could not practicably be carried out without the waiver or alteration. → Explain how your study meets this criteria:
- Will participants be provided with additional pertinent information after participation?
  - Yes
  - No → Explain why not:

**4-D. REQUEST TO WAIVE CONSENT FOR EMERGENCY RESEARCH:** Describe how the study meets the criteria for emergency research and the process for obtaining LAR consent is appropriate. See guidance at <http://www.research.vcu.edu/irb/wpp/flash/XVII-16.htm>.

N/A

## **5. GENETIC TESTING**

**If applicable, address the following issues related to Genetic Testing.**

### **5-A. FUTURE CONTACT CONCERNING FURTHER GENETIC TESTING RESEARCH**

**Describe the circumstances under which the subject might be contacted in the future concerning further participation in this or related genetic testing research.**

N/A

### **5-B. FUTURE CONTACT CONCERNING GENETIC TESTING RESULTS**

**If planned or possible future genetic testing results are unlikely to have clinical implications, then a statement that the**

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results will not be made available to subjects may be appropriate. If results might be of clinical significance, then describe the circumstances and procedures by which subjects would receive results. Describe how subjects might access genetic counseling for assistance in understanding the implications of genetic testing results, and whether this might involve costs to subjects. Investigators should be aware that federal regulations, in general, require that testing results used in clinical management must have been obtained in a CLIA-certified laboratory.

N/A

**5-C. WITHDRAWAL OF GENETIC TESTING CONSENT**

Describe whether and how subjects might, in the future, request to have test results and/or samples withdrawn in order to prevent further analysis, reporting, and/or testing.

N/A

**5-D. GENETIC TESTING INVOLVING CHILDREN OR DECISIONALLY IMPAIRED PARTICIPANTS**

Describe procedures, if any, for consenting children upon the attainment of adulthood. Describe procedures, if any, for consenting participants who are no longer decisionally impaired.

N/A

**5-E. CONFIDENTIALITY OF GENETIC INFORMATION**

Describe the extent to which genetic testing results will remain confidential and special precautions, if any, to protect confidentiality.

N/A

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**Appendix D: List of all questionnaires and scales to use in the proposed study**

**Thank you for agreeing to participate in this research to help us find out about how the use of mobile technology influences efforts to lose weight. The following questionnaire includes questions about you personally, previous experiences with mobile technology, social support, confidence in your ability to manage your health, and diet and exercise habits. There are no rights or wrong answers to any of the questions. We are interested in your honest responses. If there are questions that you prefer not to answer, simply skip that question and move on to the next item. Answer the question in the way that best describes your thoughts and behavior. Again, thank you for your help on this study.**

**1. Are you?**

- Male  Female

**2. What was your age on your last birthday? \_\_\_\_\_**

**3. Please check the response that best describes your level of education. (Mark the one that best describes you.)**

- Some high school
- High school graduate or Graduate Equivalent Degree (GED)
- Some college, but no degree
- Associate degree from an occupational, technical, vocational or academic program
- Bachelor's degree
- Some postgraduate work
- Master's degree
- Doctoral degree (e.g. JD, MD, DVM, PhD, DO, etc.)

**5. What best describes your living situation? (Mark one answer.)**

- Married
- Living with someone in a "marriage-like" relationship
- Separated or divorced
- Widowed
- Never been married

**6. Which of the following best describes you? (Please mark one answer.)**

- White
- African American or Black
- Asian
- Native Hawaiian or Pacific Islander
- American Indian, Alaskan Indian, Alaskan Native
- Other (DESCRIBE): \_\_\_\_\_

**7. Are you of Hispanic or Latino origin or descent?**

- Yes, I am of Hispanic or Latino origin or descent
- No, I am not of Hispanic or Latino origin or descent

**8. What is your estimated yearly household income?**

- < \$25,000
- \$25,000-\$50,000
- \$50,000-\$100,000
- more than \$100,000

**9. Do you have any chronic medical problems?**

- None
- Diabetes
- High blood pressure
- Arthritis
- Cancer; please specify what kind of cancer: \_\_\_\_\_
- Asthma
- Other; please explain: \_\_\_\_\_

**We'd like to know about your experience using mobile technology. Which of the following best describes you? Please mark one answer.**

**10. On average, how many phone text messages do you send per week?**

- none (I don't text)
- 1-20
- 21-100
- >100

**11. What activities do you currently use your mobile phone for? Respond to each activity.**

***Making phone call:***

\_\_\_Very \_\_\_Frequently \_\_\_Occasionally \_\_\_Rarely \_\_\_Very \_\_\_Never  
Frequently Rarely

**Listen to music:**

\_\_\_Very \_\_\_Frequently \_\_\_Occasionally \_\_\_Rarely \_\_\_Very \_\_\_Never  
Frequently Rarely

***Texting:***

\_\_\_Very \_\_\_Frequently \_\_\_Occasionally \_\_\_Rarely \_\_\_Very \_\_\_Never  
Frequently Rarely

***Use social media (e.g. Facebook or Twitter)***

\_\_\_Very \_\_\_Frequently \_\_\_Occasionally \_\_\_Rarely \_\_\_Very \_\_\_Never  
Frequently Rarely

***Accessing the internet:***

\_\_\_Very \_\_\_Frequently \_\_\_Occasionally \_\_\_Rarely \_\_\_Very \_\_\_Never  
Frequently Rarely

***Play games:***

\_\_\_Very \_\_\_Frequently \_\_\_Occasionally \_\_\_Rarely \_\_\_Very \_\_\_Never  
Frequently Rarely



**Checking email:**

\_\_\_Very \_\_\_Frequently \_\_\_Occasionally \_\_\_Rarely \_\_\_Very \_\_\_Never  
 Frequently Rarely

**Use the calendar:**

\_\_\_Very \_\_\_Frequently \_\_\_Occasionally \_\_\_Rarely \_\_\_Very \_\_\_Never  
 Frequently Rarely

**Directions: Please choose a response that best expresses *how well* each statement about eating behavior describes you.**

**12. I purposefully hold back at meals in order not to gain weight.**

\_\_\_Not at all \_\_\_Slightly \_\_\_More or Less \_\_\_Pretty Well \_\_\_ Completely

**13. I tend to eat more when I am anxious, worried, or tense.**

\_\_\_Not at all \_\_\_Slightly \_\_\_More or Less \_\_\_Pretty Well \_\_\_ Completely

**14. I count calories as a conscious means of controlling my weight.**

\_\_\_Not at all \_\_\_Slightly \_\_\_More or Less \_\_\_Pretty Well \_\_\_ Completely

**15. When I feel lonely I console myself by eating.**

\_\_\_Not at all \_\_\_Slightly \_\_\_More or Less \_\_\_Pretty Well \_\_\_ Completely

**16. I tend to eat more food than usual when I have more available places that serve or sell food.**

\_\_\_Not at all \_\_\_Slightly \_\_\_More or Less \_\_\_Pretty Well \_\_\_ Completely

**17. I tend to eat when I am disappointed or feel let down.**

\_\_\_Not at all \_\_\_Slightly \_\_\_More or Less \_\_\_Pretty Well \_\_\_ Completely

**18. I often refuse foods or drinks offered because I am concerned about my weight.**

\_\_\_Not at all \_\_\_Slightly \_\_\_More or Less \_\_\_Pretty Well \_\_\_ Completely

**19. If I see others eating, I have a strong desire to eat too.**

\_\_\_Not at all \_\_\_Slightly \_\_\_More or Less \_\_\_Pretty Well \_\_\_ Completely

**20. Some foods taste so good I eat more even when I am not hungry.**

\_\_\_ Not at all \_\_\_ Slightly \_\_\_ More or Less \_\_\_ Pretty Well \_\_\_ Completely

**21. When I have eaten too much during the day, I will often eat less than usual the following day.**

\_\_\_ Not at all \_\_\_ Slightly \_\_\_ More or Less \_\_\_ Pretty Well \_\_\_ Completely

**22. I often eat so quickly I don't notice I'm full until I've eaten too much.**

\_\_\_ Not at all \_\_\_ Slightly \_\_\_ More or Less \_\_\_ Pretty Well \_\_\_ Completely

**23. If I eat more than usual during a meal, I try to make up for it at another meal.**

\_\_\_ Not at all \_\_\_ Slightly \_\_\_ More or Less \_\_\_ Pretty Well \_\_\_ Completely

**24. When I'm offered delicious food, it's hard to resist eating it even if I've just eaten.**

\_\_\_ Not at all \_\_\_ Slightly \_\_\_ More or Less \_\_\_ Pretty Well \_\_\_ Completely

**25. I eat more when I'm having relationship problems.**

\_\_\_ Not at all \_\_\_ Slightly \_\_\_ More or Less \_\_\_ Pretty Well \_\_\_ Completely

**26. When I'm under a lot of stress, I eat more than I usually do.**

\_\_\_ Not at all \_\_\_ Slightly \_\_\_ More or Less \_\_\_ Pretty Well \_\_\_ Completely

**27. When I know I'll be eating a big meal during the day, I try to make up for it by eating less before or after that meal.**

\_\_\_ Not at all \_\_\_ Slightly \_\_\_ More or Less \_\_\_ Pretty Well \_\_\_ Completely

**The following questions are aimed at helping us understand how confident you are that you can manage your health—particularly your eating and exercise behaviors. Again, there are no right or wrong answers. Choose the answer that best reflects your beliefs.**

**28. How confident are you that you can reduce your portion sizes at meals and at snack each day?**

- very confident
- somewhat confident
- somewhat non-confident
- very non-confident
- Not at all confident

**29. How confident are you that you can increase the number of fruits and vegetables you eat daily?**

- very confident
- somewhat confident
- somewhat non-confident
- very non-confident
- Not at all confident

**30. How confident are you that you can reduce the amount of butter and other fats or oils that you eat each day?**

- very confident
- somewhat confident
- somewhat non-confident
- very non-confident
- Not at all confident

**31. How confident are you that you can eat only a very small amount of fried food like fried chicken, French fries, potato chips, or other fried food each week?**

- very confident
- somewhat confident
- somewhat non-confident
- very non-confident
- Not at all confident

**32. How confident are you that you can reduce or omit drinking sugary drinks like Kool-Aid, colas, sugared teas and coffee, or other sugared soft drinks?**

- very confident
- somewhat confident
- somewhat non-confident
- very non-confident
- Not at all confident

**33. How confident are you that you can reduce or omit fats (butter, fatty meats or oils) in cooking vegetables, beans, or frijoles?**

- very confident
- somewhat confident
- somewhat non-confident
- very non-confident
- Not at all confident

**34 How confident are you that you can substitute lower calorie food—like fruit, vegetables, or yogurt—for high-calorie snacks, like cakes, pies, or ice cream?**

- very confident
- somewhat confident
- somewhat non-confident
- very non-confident
- Not at all confident

**35. How confident are you that you can reduce the amount of time you sit and watch TV?**

- very confident
- somewhat confident
- somewhat non-confident
- very non-confident
- Not at all confident

**36. How confident are you that you can increase time spent in physical activity while at home, given your current family responsibilities?**

- very confident
- somewhat confident
- somewhat non-confident
- very non-confident
- Not at all confident

**37. How confident are you that you can increase time spent in physical activity by walking or other activities outside the home?**

- very confident
- somewhat confident
- somewhat non-confident
- very non-confident
- Not at all confident

**38. How confident are you that you can select lower-calorie food at a fast-food restaurant?**

- very confident
- somewhat confident
- somewhat non-confident
- very non-confident
- Not at all confident

**The next set of questions asks about your attitude towards technology—particularly mobile phones. Choose the best answer that describes you.**

**40. Using a mobile phone improves the quality of the work I do.**

- Strongly agree
- agree
- neutral
- disagree
- strongly disagree

**41. Using a mobile phone enables me to accomplish tasks more quickly**

- Strongly agree
- agree
- neutral
- disagree
- strongly disagree

**42. The interaction with mobile phone is clear and understandable**

- Strongly agree
- agree
- neutral
- disagree
- strongly disagree

**43. Overall I find the mobile phone features easy-to-use**

- Strongly agree
- agree
- neutral
- disagree
- strongly disagree

**44. A mobile phone is very essential device that I use every day**

- Strongly agree
- agree
- neutral
- disagree
- strongly disagree

**Instructions: This scale is made up of a list of statements each of which may or may not be true about you. For each statement circle "definitely true" if you are sure it is true about you and "probably true" if you think it is true but are not absolutely certain. Similarly, you should circle "definitely false" if you are sure the statement is false and "probably false" if you think it is false but are not absolutely certain.**

**45. If I wanted to go on a trip for a day (for example, to the country or mountains), I would have a hard time finding someone to go with me.**

- definitely false
- probably false
- probably true
- definitely true

**46. I feel that there is no one I can share my most private worries and fears with.**

- definitely false
- probably false
- probably true
- definitely true

**47. If I were sick, I could easily find someone to help me with my daily chores.**

- definitely false
- probably false
- probably true
- definitely true

**48. There is someone I can turn to for advice about handling problems with my family.**

- definitely false
- probably false
- probably true
- definitely true

**49. If I decide one afternoon that I would like to go to a movie that evening, I could easily find someone to go with me.**

- definitely false
- probably false
- probably true
- definitely true

**50. When I need suggestions on how to deal with a personal problem, I know someone I can turn to.**

- definitely false
- probably false
- probably true
- definitely true

**51. I don't often get invited to do things with others.**

- definitely false
- probably false
- probably true
- definitely true

**52. If I had to go out of town for a few weeks, it would be difficult to find someone who would look after my house or apartment (the plants, pets, garden, etc.).**

- definitely false
- probably false
- probably true
- definitely true

**53. If I wanted to have lunch with someone, I could easily find someone to join me.**

- definitely false
- probably false
- probably true
- definitely true

**54. If I was stranded 10 miles from home, there is someone I could call who could come and get me.**

- definitely false
- probably false
- probably true
- definitely true

**55. . If a family crisis arose, it would be difficult to find someone who could give me good advice about how to handle it.**

- definitely false
- probably false
- probably true
- definitely true



**56. If I needed some help in moving to a new house or apartment, I would have a hard time finding someone to help me.**

- definitely false
- probably false
- probably true
- definitely true

**57. I feel a connection to the others participating in the current wellness program**

- definitely false
- probably false
- probably true
- definitely true

**58. Others participants in my current wellness program may influence my healthy behaviors**

- definitely false
- probably false
- probably true
- definitely true

**59. I receive support for participating in regular physical activity from my wellness program**

- definitely false
- probably false
- probably true
- definitely true

**60. I receive support for making healthy food choices from my wellness program.**

- definitely false
- probably false
- probably true
- definitely true

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

\_\_\_\_\_ **days per week**

No vigorous physical activities → **Skip to question 3**

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

\_\_\_\_\_ **hours per day**

\_\_\_\_\_ **minutes per day**

Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

3. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

\_\_\_\_\_ **days per week**

No moderate physical activities → *Skip to question 5*

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

\_\_\_\_\_ **hours per day**

\_\_\_\_\_ **minutes per day**

Don't know/Not sure

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

\_\_\_\_\_ **days per week**

No walking → *Skip to question 7*

6. How much time did you usually spend **walking** on one of those days?

\_\_\_\_\_ **hours per day**

\_\_\_\_\_ **minutes per day**

Don't know/Not sure

*Please continue—just a few more questions*

The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

\_\_\_\_\_ **hours per day**

\_\_\_\_\_ **minutes per day**

Don't know/Not sure

**Evaluation of Tailored Text Messaging**  
**(Administered to the intervention group at week 12)**

We would appreciate your feedback on tailored text messaging. Please check the response that best describes your opinion on the statement and include written comments in the space provided.

**1. Did you think that the text messaging challenges were motivating?**

\_\_\_ Not at all                      \_\_\_ Somewhat                      \_\_\_ Very Much

Comments: \_\_\_\_\_  
\_\_\_\_\_

**2. Was the frequency of the text messaging acceptable?**

\_\_\_ Not at all                      \_\_\_ Somewhat                      \_\_\_ Very Much

Comments: \_\_\_\_\_  
\_\_\_\_\_

**3. Was the timing (time of day?) of the messages adequate to allow you to complete the challenges?**

\_\_\_ Not at all                      \_\_\_ Somewhat                      \_\_\_ Very Much

Comments: \_\_\_\_\_  
\_\_\_\_\_

**4. Were you able to complete the challenges?**

\_\_\_ Not at all                      \_\_\_ Somewhat                      \_\_\_ Very Much

Comments: \_\_\_\_\_  
\_\_\_\_\_

**5. Did the text messages help you make good choices about your eating and exercise?**

\_\_\_ Not at all                      \_\_\_ Somewhat                      \_\_\_ Very Much

Comments: \_\_\_\_\_  
\_\_\_\_\_

***Thank you for your participation!!***



## RESEARCH SUBJECT INFORMATION AND CONSENT FORM

### **TITLE: MOBILE PHONE TEXT MESSAGING AS ADJUNCT TO A COMMUNITY-BASED WEIGHT MANAGEMENT PROGRAM**

**VCU IRB NO.:**

#### **INTRODUCTION**

You are being asked to take part in a research study to help healthcare providers to better understand how mobile technology may affect the adoption of healthy behaviors and affect the daily lifestyle of people trying to reach their healthy body weight.

This consent form may contain words that you do not understand. Please ask the study staff to explain any words that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

In this consent form the word “you” means the person taking part in the study. It is important that the person taking part in the study is the person who answers the questions.

#### **PURPOSE OF THE STUDY**

The purpose of this research study is to find out about the effect of mobile technology on adoption of healthy eating and exercise behaviors in a weight loss group and ultimately assess the effect of mobile technology on change in body weight. You are being asked to participate in this study because you are enrolled in a wellness program for weight management.

#### **DESCRIPTION OF THE STUDY AND YOUR INVOLVEMENT**

The study explores the utility of text messages in helping participants make healthy lifestyle choices. Some people will receive text messages and some will not. The study will last for 12 weeks and consists of 2 groups with an average of 15 participants in each group.

If you decide to be in this research study, you will be asked to sign this consent form after you have had all your questions answered. In this study, your height and weight measurement will be recorded by the research personnel (Dr. Salyer or Ms. BouHaidar). You will be asked to fill out some questionnaires which will take approximately 30 minutes. These questionnaires contain information about you, how you feel about technology, and how you manage your diet and exercise routine. These questionnaires will be re-administered in 12 weeks.

#### **RISKS AND DISCOMFORTS**

Sometimes talking about these subjects may causes people to become upset. Some questions will ask about things that may remind you of unpleasant feelings. You do not have to answer any questions you do not want to answer, or makes you uncomfortable.



## **BENEFITS TO YOU AND OTHERS**

You may not get any direct benefit from this study, but, the information we learn from participants may help us design better wellness programs to manage body weight.

## **COSTS**

There are no costs for participating in this study other than the time you will spend in the groups and filling out questionnaires which will be approximately 30 minutes at the beginning and at the end of the study in 12 weeks. In case there was any additional expenses related to receiving text messages, the related cost will be reimbursed by the study personnel (when participants do not have an unlimited text messages option with their mobile phone carrier).

## **PAYMENT FOR PARTICIPATION**

Upon enrollment, you will receive a \$10.00 gift card at a local mall for filling out the questionnaires. At the end of the study at 12 weeks, there will be a raffle drawing that entitles one participant in each group to a complementary session with a personal trainer offered by the Recreation sports center here at the VCU.

## **ALTERNATIVES**

The alternative is to not participate in the study.

## **CONFIDENTIALITY**

Potentially identifiable information about you will consist of your phone number. Data is being collected only for research purposes. Your data will be identified by ID numbers not names, and stored separately in a locked research area. All personal identifying information will be kept in password protected files and these files will be deleted after completion of the research study. Other records (questionnaire, height and weight) will be kept in a locked file cabinet after the study ends and will be destroyed after five years. Access to all data will be limited to study personnel. A data and safety monitoring plan is established.

We will not share the answers you give us; however, information from the study and the consent form signed by you may be looked at or copied for research or legal purposes by Virginia Commonwealth University. What we find from this study may be presented at meetings or published in papers, but your name will not ever be used in these presentations or papers.

## **VOLUNTARY PARTICIPATION AND WITHDRAWAL**

You do not have to participate in this study. If you choose to participate, you may stop at any time without any penalty. You may also choose not to answer particular questions that are asked in the study.

## QUESTIONS

In the future, you may have questions about your participation in this study. If you have any questions, complaints, or concerns about the research, contact:

Jeanne Salyer, RN, PhD  
School of Nursing  
Virginia Commonwealth University  
(804) 828-3373

Claudia BouHaidar, RN, MSN  
School of Nursing  
Virginia Commonwealth University  
(804) 502-0359

If you have any questions about your rights as a participant in this study, you may contact:

Office for Research  
Virginia Commonwealth University  
800 East Leigh Street, Suite 113  
P.O. Box 980568  
Richmond, VA 23298  
Telephone: 804-827-2157

You may also contact this number for general questions, concerns or complaints about the research. Please call this number if you cannot reach the research team or wish to talk to someone else. Additional information about participation in research studies can be found at <http://www.research.vcu.edu/irb/volunteers.htm>.

## CONSENT

I have been given the chance to read this consent form. I understand the information about this study. Questions that I wanted to ask about the study have been answered. My signature says that I am willing to participate in this study. I will receive a copy of the consent form once I have agreed to participate.

---

Participant name printed

Participant signature

Date

---

Name of Person Conducting Informed Consent  
Discussion / Witness  
(Printed)

---

Signature of Person Conducting Informed Consent  
Discussion / Witness

---

Date

---

Principal Investigator Signature (if different from above)

---

Date

# VCU Memo

V i r g i n i a C o m m o n w e a l t h U n i v e r s i t y

Office of Research Subjects Protection  
Bio-Tech Research Park, Building 1  
800 E. Leigh St., Ste.#114  
P.O. Box 980568  
Richmond, Virginia 23298-0568

DATE: April 24, 2012

TO: Jeanne Salyer, RN, PhD  
Adult Health and Nursing Systems

FROM: Andrea Hastillo, MD  
Chairperson, VCU IRB Panel C  
Box 980568

*Nicholas Hayward  
for  
AH*

RE: VCU IRB #: HM14343

**Title: Mobile Phone Text Messaging As Adjunct To A Community-Based Weight Management Program**

On April 19, 2012, the following research study was approved by expedited review according to 45 CFR 46.110 Category 7. This approval reflects the revisions received in the Office of Research Subjects Protection on April 19, 2012. This approval includes the following items reviewed by this Panel:

**RESEARCH APPLICATION/PROPOSAL:** None

**PROTOCOL:** Mobile Phone Text Messaging As Adjunct To A Community-Based Weight Management Program – Research Plan Template, Version 1 dated 3/26/12-stamped received 3/30/12

- Appendix B: Investigators Completed Data Collection Form, Version #1 dated 3/26/12-stamped received 3/30/12
- Appendix D: List of All Questionnaires and Scales to use in the Proposed Study, Version 1 dated 4/19/12-stamped received 4/19/12

**HIPAA PROCESS:**

The following pathways for accessing and/or using PHI have been approved:

- De-identified Data

**CONSENT/ASSENT (attached):**

- Research Subject Information and Consent Form, Version #1-stamped received 4/19/12; 4 pages

**ADDITIONAL DOCUMENTS:**

- Study Personnel Roster, Version Date 1/3-26-12-stamped received 3/30/12

**This approval expires on March 31, 2013.** Federal Regulations/VCU Policy and Procedures require continuing review prior to continuation of approval past that date. Continuing Review report forms will be mailed to you prior to the scheduled review.

The Primary Reviewer assigned to your research study is Christine DeWilde, RN. If you have any questions, please contact Ms. DeWilde at [dewildec@vcu.edu](mailto:dewildec@vcu.edu), 628-5710; or you may contact Ingrid Rosiuta, IRB Coordinator, VCU Office of Research Subjects Protection, at [IRBPanelC@vcu.edu](mailto:IRBPanelC@vcu.edu) or 827-1446.

Attachment – Conditions of Approval

### ***Conditions of Approval:***

In order to comply with federal regulations, industry standards, and the terms of this approval, the investigator must (*as applicable*):

1. Conduct the research as described in and required by the Protocol.
2. Obtain informed consent from all subjects without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate (unless Waiver of Consent is specifically approved or research is exempt).
3. Document informed consent using only the most recently dated consent form bearing the VCU IRB "APPROVED" stamp (unless Waiver of Consent is specifically approved).
4. Provide non-English speaking patients with a translation of the approved Consent Form in the research participant's first language. The Panel must approve the translated version.
5. Obtain prior approval from VCU IRB before implementing any changes whatsoever in the approved protocol or consent form, unless such changes are necessary to protect the safety of human research participants (e.g., permanent/temporary change of PI, addition of performance/collaborative sites, request to include newly incarcerated participants or participants that are wards of the state, addition/deletion of participant groups, etc.). Any departure from these approved documents must be reported to the VCU IRB immediately as an Unanticipated Problem (see #7).
6. Monitor all problems (anticipated and unanticipated) associated with risk to research participants or others.
7. Report Unanticipated Problems (UPs), including protocol deviations, following the VCU IRB requirements and timelines detailed in VCU IRB WPP VIII-7:
8. Obtain prior approval from the VCU IRB before use of any advertisement or other material for recruitment of research participants.
9. Promptly report and/or respond to all inquiries by the VCU IRB concerning the conduct of the approved research when so requested.
10. All protocols that administer acute medical treatment to human research participants must have an emergency preparedness plan. Please refer to VCU guidance on <http://www.research.vcu.edu/irb/guidance.htm>.
11. The VCU IRBs operate under the regulatory authorities as described within:
  - a) U.S. Department of Health and Human Services Title 45 CFR 46, Subparts A, B, C, and D (for all research, regardless of source of funding) and related guidance documents.
  - b) U.S. Food and Drug Administration Chapter I of Title 21 CFR 50 and 56 (for FDA regulated research only) and related guidance documents.
  - c) Commonwealth of Virginia Code of Virginia 32.1 Chapter 5.1 Human Research (for all research).

## RESEARCH SUBJECT INFORMATION AND CONSENT FORM

**TITLE: MOBILE PHONE TEXT MESSAGING AS ADJUNCT TO A  
COMMUNITY-BASED WEIGHT MANAGEMENT PROGRAM**



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**APPROVED**

CD /IR /4.19.12

## **BENEFITS TO YOU AND OTHERS**

You may not get any direct benefit from this study, but, the information we learn from participants may help us design better wellness programs to manage body weight.

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**APPROVED**

CD / IR / 4.19.12



**QUESTIONS**

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Jeanne Salyer, RN, PhD  
School of Nursing  
Virginia Commonwealth University  
(804) 828-3373

Claudia BouHaidar, RN, MSN  
School of Nursing  
Virginia Commonwealth University  
(804) 502-0359

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---

Participant name printed

Participant signature

Date

---

Name of Person Conducting Informed Consent  
Discussion / Witness  
(Printed)

**APPROVED**

CD / IR / 4.19.12

---

Signature of Person Conducting Informed Consent  
Discussion / Witness

---

Date

---

Principal Investigator Signature (if different from above)

---

Date

**APPROVED**

CD / IR / 4.19.12

## Appendix: Doctoral student Biosketch

### BIOGRAPHICAL SKETCH

USE ONLY FOR INDIVIDUAL PREDOCTORAL and POSTDOCTORAL FELLOWSHIPS. DO NOT EXCEED FOUR PAGES.

NAME Claudia Hakme BouHaidar		POSITION TITLE PhD candidate	
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Lebanese University in Lebanon	B.S.N.	1990-1994	Nursing
Lebanese University	M.S.N.	2000-2002	Nursing
Virginia Commonwealth University	PhD (candidate)	2007-expected December, 2012	Nursing

Please refer to the application instructions in order to complete sections A, B, and C of the Biographical Sketch.

ACTIVITY/OCCUPATION	BEGINNING DATE (mm/yy)	ENDING DATE (mm/yy)	FIELD	INSTITUTION/COMPANY	SUPERVISOR/ EMPLOYER
Clinical Nurse	05/2009	05/2010	Emergency preparedness	Medical College of Virginia	Robin Luffman
Staff Nurse, Transplant ICU	03/2006	06/2007	Nursing	Medical College of Virginia	Margaret Schaeffer
Nurse Educator & Clinical Instructor	09/2001	12/2003	Nursing Education	Lebanese Red Cross School of Nursing	Georgette Chelala
Nurse Specialist	09/1997	12/1998	Nutrition & Weight Management	Metabolic Center, Lebanon	Naji Torbay
Staff Nurse, Medical Respiratory ICU	09/1996	09/1997	Nursing	El-Youssef Hospital, Lebanon	Omar Ayache
Staff Nurse, Operating Room	08/1994	09/1996	Nursing	St Charles Hospital, Lebanon	Samia Abi-Haydar

#### A. Membership in Professional Societies:

Southern Nursing Research Society, 2009  
Obesity Society, 2009 - present

## B. Publications

Haddad, L., Shotar, A., Younger, J., Alzyoud, S., & **Bouhaidar, C.** (2011). Screening for domestic violence in Jordan: Validation of an arabic version of a domestic violence against women questionnaire. *International Journal of Women's Health*, 3, 79-86.

Abdelsalam, H., Alam, M., **Hakme, C.**, Masri, R. (2002) Effects of Hospital Accreditation on the quality of care in Intensive Care units in Lebanon. Dissertation, Lebanese University, Lebanon.

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## C. Poster Presentation

Poster presentation at the annual meeting of the Southern Nursing Research Society in Austin, TX, 2011. "Effects of self-efficacy on weight management in premenopausal women: A conceptual framework".