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Recruiting young adults into a weight loss trial: Report of protocol development and recruitment results

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Abstract

Obesity has spread to all segments of the U.S. population. Young adults, aged 18-35, are rarely represented in clinical weight loss trials. We conducted a qualitative study to identify factors that may facilitate recruitment of young adults into a weight loss intervention trial. Participants were 33 adults aged 18-35 yrs with BMI > 25 kg/m². Six group discussions were conducted using the nominal group technique. Health, social image, and "self" factors such as emotions, self-esteem, and confidence were reported as reasons to pursue weight loss. Physical activity, dietary intake, social support, medical intervention, and taking control (e.g. being motivated) were perceived as the best weight loss strategies. Incentives, positive outcomes, education, convenience, and social support were endorsed as reasons young adults would consider participating in a weight loss

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study. Incentives, advertisement, emphasizing benefits, and convenience were endorsed as ways to recruit young adults. These results informed the Cellphone Intervention for You (CITY) marketing and advertising, including message framing and advertising avenues. Implications for recruitment methods are discussed.

Keywords

Obesity; young; adults; recruitment; methods; trial

INTRODUCTION

The obesity epidemic has spread to all segments of our population [1]. Obesity has become a major health problem for adults 18-35 years, with evidence of an increased incidence of obesity-related diseases such as Type 2 diabetes mellitus in this age group [2-5]. Interventions in early adulthood may help decrease the long-term health consequences of this epidemic. During the last decade, several trials indicate that weight loss can be achieved, and to some degree sustained, with behavioral interventions that incorporate personal contact, social support, and motivational counseling [6-8]. However, young adults

35 years of age are underrepresented in behavioral weight loss trials [9], limiting generalizability of the findings to this age group. For example, a systematic review of weight loss studies in adults aged 18-25 years suggested that small sample sizes (range 16-67 participants) in the included studies reflect recruitment and retention challenges experienced by the investigators [10].

Traditional methods for recruitment into clinical trials may not be suited to this age group, and investigators may need to modify their recruitment strategies in order to reach young adults and to increase interest in participation in this type of trial. To our knowledge, no studies have been conducted to elucidate the perception of young adults regarding the most effective recruitment and retention strategies. In this paper, we report on the development and outcomes of the recruitment protocol for the Cellphone Intervention for You (CITY) trial, a randomized controlled trial of a weight loss intervention directed at young adults.

METHODS AND PROCEDURES

Design

The Cellphone Intervention for You Trial (CITY) is a National Institute of Health-National Heart, Lung, and Blood Institute (NIH- NHLBI)-sponsored randomized controlled trial testing an innovative cell phone intervention for weight loss in young adults. During the formative research phase of the trial, we conducted 6 group discussions with members of the target population to inform development of recruitment strategies. We used the nominal group technique (NGT), a structured variation of focus group methodology in which a small-group discussion is used to reach consensus [11, 12]. This qualitative process generates data that is quantitative, objective, and prioritized [12]. In addition, the NGT facilitates the collection of data that is a reflection of the group's preference and reduces the risk that one person will dominate the discussion.

Recruitment Procedures

Overweight/obese (Body Mass Index [BMI] 25 kg/m^2) adults aged 18-35 years and were available the days and times offered. Participants were recruited from the local community and universities. Recruitment methods included flyers posted on the Duke University campus and local businesses, including coffee shops that are popular among young adults.

We also advertised, in the local and university newspapers including the newspapers websites, posted information on websites (e.g., Duke University websites such as http://www.dukehealth.org/clinicaltrials), utilized referrals from colleagues at North Carolina Central University (NCCU) and North Carolina State University (NCSU), sent electronic mail and got referrals through word of mouth. Participants received a \$25 gift card for participation in a group discussion. The study was approved by the Duke University Institutional Review Board. All participants provided written informed consent.

Six group discussions (G1-G6) were conducted: To increase diversity, two groups were recruited and conducted at North Carolina Central University a historically black university located in Durham, North Carolina. The remaining four groups were conducted at the Sarah W. Stedman Nutrition and Metabolism Center located on the Center for Living campus at Duke University, Durham, North Carolina. Two of the groups were conducted with African American participants. One group was conducted with Hispanic/Latino participants. Nomore than six group discussions were conducted because saturation (i.e., when the researcher is no longer hearing new information) was reached and additional groups were less likely to provide new information.

Procedures

The group discussion sessions lasted approximately 90-120 minutes and were facilitated by a CITY co-investigator, trained and experience conducting group discussions using NGT. One Co- investigator was present during each group to provide assistance to the facilitator. After obtaining informed consent, the facilitator proceeded as follows: 1) introduced the research team; 2) explained the purpose of the group discussion; 3) explained why they were asked to participate; 4) discussed ground rules; 5) conducted an icebreaking activity and 6) explained the process for gathering the information from the group using the NGT.

Four questions were generated by the study team to inform the development of recruitment strategies that could be effective in young adults and to advise the investigators regarding strategies to recruit young adults into CITY: 1) "What are some reasons people your age care about their weight?"; 2) "What are some ways people your age can control their weight"; 3) "What would make people like you participate in a weight loss study?"; 4) "What could we do to recruit people your age into a weight loss study?"

Conduct of the group discussions using the modified NGT in this study involved several steps: 1) Each question was posed to the participants, who generated answers (attributes) individually and wrote them on an index card; 2) The facilitator created a list of all attributes listed on the index cards; 3) The facilitator asked the group to clarify ambiguous responses; 4) In a group process, participants grouped similar attributes into themes and named each theme; and 5) Individually, participants ranked the top three themes from the comprehensive list (1 for the most important and 3 for the least important).

During the discussions, the facilitator and the assistant avoided making any comments or suggestions regarding participant responses, serving only as a moderator/facilitator to the group conversation. At the end of each group discussion, demographic information was collected with a brief self-administered survey.

Group Discussion Data Analysis

Three investigators met to review and discuss themes generated by the group discussions. Themes generated by the participants were grouped by the investigators into higher order themes based on similarity. (e.g., "physiological" named by one group included attributes such as health and so was grouped with "health" named by other groups) through a consensual process. Themes were subsequently reviewed by a fourth investigator. For each

theme generated by each group, rankings were averaged across participants. Because each participant ranked his/her three most important themes, some themes were not ranked by some or all participants. Thus, the rankings provide information on the importance of each theme relative to the other themes generated both within and between groups.

RESULTS

Group Discussion Results

A total of 83 individuals responded to our recruitment efforts. Of those, 33 met inclusion criteria and were scheduled to participate in a group discussion. The range of participants in each group discussion was 3-12, with a mean of 5. The mean age was 27.4 years (SD, 5.6) years and the mean BMI was 31.6 kg/m² (SD, 5.1). Sixteen (55%) were students. Ten (37%) were white, 16 (59%) African American, 1 (4%) Asian. Three (10%) self-identified as Hispanic/Latino. Twenty two (76%) were women.

Participants' perceptions of reasons young adults care about their weight (question 1)

In response to the first question, "What are some reasons people your age care about their weight?" the three higher-order themes were health, social image, and "self" factors. When discussing attributes related to health, participants mentioned energy level, reducing health risk, and fewer health issues during pregnancy. Attributes related to social image included sex appeal, popularity, appearance, and good looks. Attributes related to self factors included self-esteem, confidence, and body image. The health and social image themes were ranked by all groups (G1-G6). Health was highly ranked (average ranking close to 1) by 5 out of 6 groups (G1, G2, G3, G5, G6), whereas social image was highly ranked by only one group (G4). The self factors theme was ranked by 5 of the groups and was highly ranked by one group (G1). (Table 1)

Participants' perceptions of ways people their age can control their weight (question 2)

In response to the second question, "What are some ways people your age can control their weight," the six higher-order themes were physical activity, dietary habits, social support, medical intervention, take control, and others. When discussing attributes related to physical activity, the groups mentioned playing sports, exercise, and active living. Attributes related to dietary habits included eating healthy, having a balanced nutrition, monitoring portion sizes, and keeping a food diary. Two groups mentioned attributes related to social support, such as being around fit people, support groups, and encouragement from family/friends. Two groups mentioned attributes related to medical interventions, such as medical help, weight loss surgery, and prescriptions. Also, two groups mentioned attributes related to taking control, including motivation, defining goals, and self-control. Four groups mentioned other attributes related to ways people their age can control their weight, including rest, weight loss programs, realistic parameters to measure individual health, starvation, and vomiting. The physical activity and dietary habits themes were ranked by all groups (G1-G6). Physical activity was highly ranked by four groups (G1, G2, G3, G5), whereas dietary habits was highly ranked by one group (G4). The theme medical intervention was highly ranked by one group (G6), and the theme take control was highly ranked by another (G4). (Table 2)

Participants' perceptions of reasons young adults would participate in a weight loss study (question 3)

In response to the third question, "What would make people like you participate in a weight loss study?" the seven higher-order themes were incentives, positive outcomes, education, convenience, social support, self factors, and other. Attributes related to incentives included

gift cards or tickets to Duke games, money, food, rewards, and course credits. When discussing attributes related to positive outcomes the groups mentioned losing weight, the study might help others, and gaining more confidence. Attributes mentioned in the education theme included receiving health advice and information on weight loss. While discussing attributes related to convenience, participants mentioned ease of participating, not being time consuming, and fitting their schedule. Additional attributes discussed during the focus groups and included in the themes social support, self factors, and other included getting support, knowing somebody in the group, self-esteem, motivation, and publicize. The incentives theme was ranked by all groups (G1-G6) and was highly ranked by 4 groups (G1, G2, G3, G6). "Positive outcomes" was ranked by 5 groups (G1, G2, G4, G5, G6) and was highly ranked by one group (G5). The themes education and convenience were highly ranked by one group each, G6 and G3, respectively. (Table 3)

Participants' perceptions of what researchers/investigators can do to recruit young adults into weight loss studies (question 4)

In response to the fourth question, "What could we do to recruit people your age into a weight loss study?" the four higher-order themes were: offer incentives, advertise, emphasize benefits, and make it convenient. Attributes related to incentives were similar to those discussed in question 3 and included "plenty of money" ("the more the better") and free food. Attributes included in the advertise theme included flyers, websites, and social networking sites such as Facebook and Twitter. Attributes included in the emphasize benefits and make it convenient themes included eliminate misconception about research by the general public and offer flexibility with schedule and time. Only the advertise theme was ranked by all groups (G1-G6). This theme was highly ranked by two groups (G1 and G3). The theme incentives was ranked by 4 groups and was highly ranked by two of them (G1 and G6). The make it convenient theme was ranked by two groups and both ranked this theme highly (G3 and G6). (Table 4)

DISCUSSION

This manuscript describes the results of a formative research using the NGT conducted to inform recruitment strategies for an on-going randomized controlled trial of a weight loss intervention directed at young adults (18-35 years old). To our knowledge, this is the first study that gathered qualitative data to elucidate young adults' perceptions on recruitment into a weight loss study. Despite therecent report that young adults might care more about their appearance and looks than about the effects of overweight/obesity on health risks, most groups ranked health as the most important reason individuals their age care about their weight [13]. Although respondents may have emphasized this concern because the group discussions were conducted by a health care professional, this finding at the very least indicates that young adults who participated in this study are *aware* of the health consequences of being overweight/obese. This may be a reflection of the increasing awareness by the general public about the link between unhealthy weight and the development of chronic diseases such as hypertension and diabetes. The groups also ranked social image as influential; in fact, one group ranked this theme as the most important reason for losing weight.

Our findings are in line with those of other weight loss studies [14, 15]. Hank et al reported a study examining the main reasons overweight/obese working men want to lose weight. In their study, conducted with males aged 18-55, health benefits were recognized as the main factor for attempting to lose weight. However, when examined by age group, participants between the ages 30-40 considered improved appearance as their primary reason, and those between 18-29 ranked appearance second in importance to improving fitness [15]. The finding that health was reported as an important reason for losing weight suggests that

recruitment and retention strategies should incorporate the health benefits of weight loss to attract this age group into a weight loss trial.

Interestingly, physical activity was endorsed as the most important method for losing weight. This finding is in line to the recent report that young adults see physical activity, rather than energy intake, as key to weight loss. [13] Current scientific evidence shows that physical activity alone, without dietary changes, has minimal impact on weight loss and that physical activity is more important for weight maintenance and for metabolic changes such as improving insulin resistance [16]. Participants also cited incentives such as monetary compensation, free food, and rewards as reasons young adults would participate in a weight loss study. Incentives were also considered by participants as ways investigators can recruit young adults into weight loss studies. These findings are consistent with those reported in other studies in which financial rewards are motivators for study participation [17, 18].

The fact that incentives are considered an important motivator for study participation has led to debate in the field of clinical research because of the potential ethical implications of paying an individual to be part of a clinical trial. Some argue that financial motivators increase the risk of coercion of vulnerable populations such as those of lower socioeconomic status, which raises issues around the ethical principle of justice [19]. Using financial incentives for recruitment may also affect weight loss, becoming a part of the intervention that is not sustainable outside of the research context. Financial incentives may also affect the external validity of findings.

In addition to financial incentives, participants also mentioned positive outcomes, education, and convenience as motives for participation. This information can be utilized by investigators to develop programs and recruitment campaigns that incorporate and emphasize the flexibility of the program and education about weight loss.

Despite incorporating more innovative strategies mentioned by the group discussions participants such as Facebook, a traditional method, targeted mass mailing, was the most successful recruitment method for this age group. In our study, we used postcards with the message tailored to the demographic make-up of the zip codes. For example, in the areas with high number of minorities we emphasized the disproportional number of minorities affected by obesity and obesity related conditions. Mass mailing has been an extensively used and effective method for recruitment of participants into clinical trials [20--22]. In the Diabetes Prevention Program, one of the largest trials conducted to prevent chronic diseases that included lifestyle intervention, mass mailing was a successful recruitment method to recruit African Americans and across age groups [23].

In addition to mass mailing, advertisement on websites, including our institutional website (Duke Clinical Trials Website), was a successful method for recruitment of young adults into our trial. This may reflect the familiarity of this age group with the Internet. Internet has become a popular alternative to traditional methods for recruitment into clinical trials [24, 25].

The use of social networking site (Facebook) was not as successful as we expected despite the fact that we utilized the services of a local media company to develop and place the advertisement. This was a method suggested by the group discussion participants and has been proposed and used with success by other investigators [26-29]. Research is needed to identify successful methods for using social network sites for recruitment into clinical trials.

All recruitment methods come with the potential scientific and ethical issues such as fairness and selection bias. The use of social networking sites or general websites comes with the additional issue of access; people without a Facebook account, Internet access, or a

computer will not have access to this type of advertisement, potentially limiting participation of this group.

Lessons learn during formative work and CITY recruitment protocol

On the basis of our group discussion findings, the CITY recruitment protocol was developed as follows. First, we used recruitment advertisement avenues suggested by the group participants, such as websites and social network sites such as Facebook. Facebook advertisements were created and placed by a media design company. The CITY Facebook ads targeted to young adults aged 18-35 living within 25 miles of Durham, North Carolina.

In addition, two investigators presented the CITY project in two news media specials (WRAL a local television station and Univision, a Spanish language television station) providing information regarding the benefits of weight loss and the importance and implications of obesity in young adults, a method previously used by our team and also recommended by the group discussion participants.

Because the group discussion participants reported health as a major reason to lose weight, we emphasized health in our recruitment materials. The CITY website indicated that being overweight/obese is a major risk factor for the development of diabetes, hypertension, coronary artery disease, and cerebrovascular events.

Finally, despite the fact that incentives were cited as an important motivation for study participation, we mentioned but did not emphasize (e.g., via larger font or listing it first) incentives because of the potential ethical implication of financial incentives and research participation.

Using these methods, we developed a recruitment campaign that allowed us to exceed our recruitment goal of 360 (365 were randomized). The recruitment methods with the greatest yield were mass mailing 146 (40.0%), Duke clinical trials website 81 (22.2%) and word of word of mouth (friends/family/coworkers), 62 (16.9%). Only 3 (0.82%) of CITY participants were recruited using social media (Facebook).

CONCLUSION

Recruitment campaigns aiming to enroll overweight/obese adults 18 to 35 years old into a weight loss trial should consider emphasizing health benefits in their recruitment materials. Traditional recruitment methods such as targeted mass mailing are very successful method for recruitment of this age group.

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Themes, attributes, and rankings for focus group question 1 ("What are some reasons people your age care about their weight?")

Theme	Group Number, Theme (Attributes)	Rank ^a
Health	G6, Health (health, reduce health problems)	1.0
	G5, Health (health professors stress importance, be around for children, healthy older life, less medications, longer life span)	1.2
	G1 and G3, Health (long term health, fewer pregnancy issues, health, starting to think about long-term health, energy level, mobility)	1.3
	G2, Physiological (health, physically fit, maintain healthy lives)	1.5
	G4, Health Image (reduce health risk, healthy lifestyle, feel comfortable in own skin, work towards unreachable perfect body, stay healthy, experience more adverse effects from unhealthy habits, extend life)	2.6
Social image	G5, How others view us (peers evaluation, big event coming up)	1.2
	G4, Social Image (appearance, fit in with other crowds of individuals, media e.g. news, how others perceive them, society, peer pressure, baby fat is no longer a valid excuse, look good for opposite sex, people are judgmental about weight, weight keeps from finding love and doing something, for example running with kids or riding a roller coaster, be teased, a good role model to child)	1.4
	G5, Societal norms (beauty, getting jobs, see on TV)	1.8
	G3, Appearance (be able to buy cute clothes, good looks, appearance)	2.0
	G2, Societal perception (socially acceptable for women to be thinner than male counterparts, acceptance to peers, the society, increase attractiveness, attractive to others, attract opposite sex)	2.5
	G3, Role model (a good role model for kids, role model for family, support others, role model in general)	2.6
	G1, Relationship (sex appeal, partner, popularity, get a man)	2.8
	G6, Appearance (looks, appearance)	3.0
"Self"factors	G1, Emotion (self-esteem, confidence, appearance, pretty)	1.5
	G5, How we view ourselves (confidence, self-esteem, body image, cute clothes)	1.8
	G4, Self Image (self-esteem, one's well-being, afraid of being obese, look good for themselves)	1.8
	G2, Self image (appearance, availability of apparel, image issues/self-confidence)	2.0
	G6, Emotional (emotional value, relationship, think that nobody will notice them, at our age people say it is hard to lose weight)	2.0

Themes, attributes and rankings for focus group question 2 ("What are some ways people your age can control their weight")

Theme	Group Number, Theme (Attributes)	Rank ^a
Physical	G3, Exercise	1.0
activity	G2, Active lifestyle (active living, exercise, exercise consistently, walk, use public transportation, walking their pets, playing sports with their children, parking further away from school/home/work, enjoying a WiiFit)	1.0
	G5, Exercise (limit stress)	1.2
	G1, Exercise (playing sports, exercise/cardio, weight training, stay active, go out more)	1.6
	G6, Exercise (exercise, motivator-someone to do it together with)	2.0
	G4, Physical activity (exercise)	2.6
Dietary habits	G5, Diet program (medication, eating habits, eating healthier)	0.8
	G1, Diet (eat healthy, watch what to buy at store, eating plan, counting calories)	1.6
	G4, Healthy intake (eat healthy, diet diary, control eating, drink water, cut down junk food, not drink excessive alcohol, education on nutrition, healthy snack, correct eating habit, think positive not depress which lead over-eating, cook more at home, eat less, bake food instead of fry)	2.0
	G3, Diet (diet, eat less, portion sizes, more fruits, more vegetables, less snacks in between meals)	2.0
	G2, Balanced nutrition (eating in moderation, normal eating habits, eat balanced diets, avoid late-night eating, eat breakfast)	3.0
	G6, Nutritional information (don't eat after 6 pm, diets, nutritionist, being informed)	3.0
Social support	G5, Support (partner to practice healthy habits, encouragement from family/friends)	1.8
	G1, Support (being around fit peers, support group, personal trainer)	2.6
Medical intervention	G6, Prescription (pills)	1.0
Take control	G5, Self-control	1.0
	G4, Take Initiative (motivation, define goals, incentives, active)	1.6
Other	G5, Society (learn risk of overweight through media, healthier food is affordable, realistic parameters to measure individual health)	1.2
	G2, Rest (adequate sleep/rest, reduce stress)	2.0
	G3, Lifestyle (lifestyle changes, weight loss programs, support systems, help to get motivated)	3.0

Themes, attributes and rankings for focus group question 3 ("What would make people like you participate in a weight loss study?")

Theme	Group Number, Theme (Attributes)	Rank ^a
Incentives	G2, Material incentives (money, food, monetary compensation, free food, incentives like money or something similar, cash)	1.0
	G3, Incentives (monetary compensation, rewards, free/low cost exercise help, free/low cost dietitian sessions, incentives)	1.3
	G5, Incentives (money, fun, low cost, course credit, excitement)	1.4
	G1, Money (compensation, money, some type of reward)	1.5
	G6, Compensation (monetary compensation, saying if you bring a buddy you get a gift card/money, food, tickets to Duke games)	1.6
Positive outcomes	G5, Results (obtainable, testimonials, benefit, realistic, guarantee, more confidence)	1.6
	G4, Benefits (extra learning, opportunity, educational insight)	2.0
	G4, Outcomes (lose weight, possibility and reality of a healthy life, goals to look forward to)	2.2
	G1, Health (health concern, study might help)	2.3
	G2, Positive experience (to hear others' experiences, motivator from others, interaction with others in similar setting, improved self image/confidence, make it fun)	2.5
	G6, Results (lose weight, the promise of succeed)	2.6
Education	G1, Education (unable to lose weight with own strategies, might benefit others, interest in research topic, some direct benefit)	0.5
	G6, FYI (learn and get more information, information on weight)	1.6
	G5, Awareness (support people who are trying to find ways to help people)	1.8
	G2, Education (health advice, to learn weight loss techniques)	2.5
Convenience	G3, Convenience (convenient, eat health at work/neighborhood, fit into busy schedule, affordable expenses, not time consuming)	1.6
	G5, Convenience (fit schedule, with a friend)	1.6
	G1, Easy (ease of participation, free)	2.0
Social support	G4, Supportive (explain, refreshments, make it fun and interesting, getting support, low cost, knowledge, fatal risk factors due to weight, believable statistics)	2.5
Other	G3, Publicize (publicize through social networks like Facebook, quick information blasts via Twitter, e-mail updates/motivation)	3.0

Themes, attributes and rankings for focus group question 4 ("What could we do to recruit people your age into a weight loss study?")

Theme	Group Number, Theme (Attributes)	Rank ^a
Offer incentives	G1, Money (plenty of money, pay well)	1.3
	G5, Incentives (flexible time, free food, competitive, Biggest Loser, pay)	1.4
	G6, Compensation	1.6
Advertise	G3, Incentives (monetary incentives, pay people, give away something like gift certificate, give people hope that it can help them lose weight)	3.0
	G1, Advertise well (advertise in good places: flyers, campus newspaper, craigslist, gyms, Independence, websites, campus resources)	1.6
	G2, Identify susceptible population (identify susceptible population, target advertisement)	1.7
	G4, Personal (go out into school and get students, workshops, going to college campus, Open discussions, taking about it at every opportunity to get the word out, maybe do a community drive or something and give out info, go to classrooms, come to classes consistently, promote events at large gathering (Base Ball games), going out within the community, let them know the process in which they will be included, personal conversations)	1.8
	G4, Interpersonal (put in school papers, on website, put flyers up, commercials, online ads, flyers, newspapers, asking to send out emails to students)	1.9
	G2, Recruit at college/university (recruit at universities with flyers, advertise on websites, identify medium for target population such as Facebook, set up recruitment tables on campus, social services, referral from doctors, visit college campuses)	2.0
	G4, Demographics (get people in the age group to recruit)	2.1
	G2, Recruit from general population (advertise in a health magazine/newspaper, connect with radio or TV personalities, post signs on billboard, making people aware, twitter, give free seminars where people can have the experience, educate)	2.2
	G5, Advertise (school paper, social networking, e-mail, Facebook, friends, Blackboard, media, internet)	2.2
	G3 and G6, Publicity and advertise (educate about study, clarify risk of study, make center known, Twitter, Facebook, university staff announcement, flyers on college campuses, announcements in school newspapers, flyer in doctors' offices, radio station, Facebook invites, promote with other hospitals in the area)	3.0
Emphasize	G6, Visualization (explain and show benefits/results)	1.6
benefits	G5, Results	2.0
	G1, Education (eliminate misconceptions about research)	3.0
Make it convenient	G6, Encouragement (flexibility w/ schedules and times, encourage)	1.0
	G3, (convenient time/place/lots of options, flexible to sign up and be a part of, easy to follow program, not complicated, 24/7 support)	1.3