The objective of this paper is to demonstrate potential problems of relying on intention to treat analyses when initial reach is not accounted for. Archival data from seven worksites (n=10,513 employees) that completed a weight loss program was used to determine (a) the effectiveness of the program at the end of three and six months of participation, (b) the reach of the program into the eligible employee population, and (c) the proportion of the targeted employee population that ultimately benefited from the program and the degree to which they benefited (i.e., effectiveness that accounts for reach and retention). Intention to treat analyses using baseline value carried forward for participants lost to attrition revealed that participants lost a significant (p<.01), yet modest, 2.1 lbs of weight at 3 and 2.4 lbs of weight at 6 months of participation. Follow-up analyses were conducted to determine the overall proportion of the workforce that benefited (i.e., lost weight) at 6 months. Of the 1607 participants who were retained at 6 months, 1088 were successful in losing weight and lost, on average 9.4 pounds (95% CI: 8.8 to 9.9 pounds), a clinically significant 4.4% of initial body weight. Thus, 10.1% of the total employee population benefited from the weight loss program and lost a clinically relevant amount of weight. The findings of this study indicate that presenting reach by effectiveness data to the employers could help them in making more sophisticated decisions while choosing a commercial weight loss program for their employees when compared to traditional intention to treat analyses.

Descriptors: Health promotion; Weight reduction programs; Program evaluation; Obesity; Effectiveness.

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Understanding the Impact of a Weight Loss Program: the roles of reach, retention, and effectiveness
Compreendendo o Impacto de um Programa de Perda de Peso: os papéis do alcance, retenção e efetividade
Comprendiendo el Impacto de un Programa de Pérdida de Peso: los papeles del alcance, retención y efectividad
O objetivo deste artigo é demonstrar os potenciais problemas na confiança das análises usando intenção de tratamento (ITT) quando o alcance inicial não é contabilizado. Dados de arquivo de sete locais de trabalho (n=10.513 funcionários) que completaram um programa de perda de peso foram utilizados para determinar: (a) a eficácia do programa no final de três a seis meses de participação; (b) o alcance do programa na população de funcionários elegíveis; e (c) a proporção da população alvo de funcionários que, em última análise, beneficiaram-se do programa e o grau desses benefícios (como a efetividade que considera o alcance e retenção). Análises de ITT utilizando o valor de peso inicial para participantes perdidos e desistência revelou que os participantes perderam uma significativa (p<0,01), porém modesta, quantidade de peso em três meses (0,95 quilos) e em seis meses (1,09 quilos) de participação. A seguir foram realizadas análises para determinar a proporção total da força de trabalho que se beneficiou (peso perdido) em 6 meses. De 1.607 participantes que foram mantidos por pelo menos 6 meses, 1088 foram bem sucedidos na perda de peso apresentando uma perda média de 4,3 kg (95% CI: 4,0 a 4,5Kg), indicando uma perda clinicamente significativa de 4,4% do peso corporal inicial. Assim, 10,1% da população total de funcionários se beneficiaram com o programa de perda de peso e perderam uma quantidade clinicamente relevante de peso. Os resultados deste estudo indicam que a presença de dados de alcance combinados com dados de efetividade podem auxiliar empregadores na tomada de decisões mais sofisticadas ao escolher um programa de perda de peso comercial para os seus funcionários, quando comparado à análise tradicional de ITT.

Descrições: Promoção da saúde; Programas de redução de peso; Avaliação de programas e projetos de saúde; Obesidade; Efetividade.

El objetivo de este artículo es demostrar los potenciales problemas en la confianza de los análisis usando la intención de tratamiento (ITT) cuando el alcance inicial no es contabilizado. Datos de archivo de siete locales de trabajo (n=10.513 funcionarios) que completaron un programa de pérdida de peso fueron utilizados para determinar: (a) la eficacia del programa al final de tres a seis meses de participación; (b) el alcance del programa en la población de funcionarios elegibles; y (c) la proporción de la población albo de funcionarios que en último análisis, se beneficiaron del programa y el grado de esos beneficios (como la eficacia que considera el alcance y retención). Análisis de ITT utilizando el valor de peso inicial para participantes perdidos en la desistencia reveló que los participantes perdieron una significativa (p>0,01), aunque modesta, cantidad de peso en tres meses (0,95 Kilos) y en seis meses (1,09 Kilos) de participación. Luego fueron realizados análisis para determinar la proporción total del de la fuerza de trabajo que se benefició (peso perdido) en 6 meses. De los 1607 participantes que fueron mantenidos por lo menos por 6 meses, 1088 tuvieron éxito en la pérdida de peso presentando una pérdida media de 4,3 kg (95% CI: 4,0 a 4,5Kg), indicando una pérdida clinicamente significativa de 4,4% del peso corporal inicial. Así, 10,1% de la población total de funcionarios se beneficiaron con el programa de pérdida de peso y perdieron una cantidad clinicamente relevante de peso. Los resultados de este estudio indican que la presencia de datos de alcance combinados con datos de eficacia pueden auxiliar empleadores en la tomada de decisiones más sofisticadas al elegir un programa de pérdida de peso comercial para sus funcionarios, comparado al análisis tradicional de ITT.

Descriptores: Promoción de la salud; Programas de reducción de peso; Evaluación de programas y proyectos de salud; Obesidad; Efetividad.
INTRODUCTION

There is clear evidence that the prevalence of overweight and obesity reflects an international epidemic and that it leads to serious issues that influence health, personal and society costs, and the productivity of a workforce.

However, for a worksite-based weight management intervention to have a strong impact it must reach a broad proportion of the overweight and obese employee population.

As a result a number of researchers have attempted to improve the reach of programs by offering interventions that can be delivered electronically. Although the assumption is that internet-based programs will have broader reach (due in part to removing the barrier of making time for small group meetings) there is a paucity of literature that demonstrates the number of employees that are reached by internet based programs.

For example, of six studies reviewed that used internet based health promotion interventions at worksites, only three studies reported the reach of the intervention which ranged from six to 60.0% of the population. Further, reach is defined as a temporally anchored variable (e.g., reach=the number, proportion, and representativeness of participants when they join the program). This definition may be somewhat limited in that those reached at the beginning of a program are usually not the same folks who are retained throughout the program.

A number of studies conducted in the past report their effectiveness in terms of mean number of pounds lost by the participants. To account for low retention, intention to treat analysis was considered necessary to maintain internal validity. Intention to treat analyses are also regularly used to determine effectiveness because they include all participants who began the program and impute data for follow-up to account for participants who were lost to attrition over the course of a program.

From a RE-AIM perspective, reach and effectiveness information are needed. To combine reach and effectiveness, as described above, researchers could simply report that a certain number and proportion of the overweight and obese employee population that engaged in the program and then the magnitude of weight loss that resulted, on average, from the intention to treat analysis.

However, that could mask significant results for a small proportion of the worksite population. For example, using findings from a systematic review of worksite weight loss trials an employer could read that the average weight loss per participating employee is approximately three and a half pounds at six months (using an intention to treat approach) and that approximately 20.0% of employees participated. This information would hardly be compelling for a worksite wellness coordinator interested in implementing a weight loss program.

In this paper we propose the use of data analytic techniques that account for the Reach and Effectiveness dimensions of the RE-AIM framework as well as retention over three and six months. We used an archival data set from a commercially available worksite-based, internet-delivered weight loss program. The goal of this study was to determine the reach of the program into the worksite populations and examine effectiveness within the context of reach and retention (i.e., proportion of the targeted employee population that ultimately benefited from the program and the degree to which they benefited).

METHOD

This is an archival records study of a commercially available worksite-based, internet-delivered weight loss program (IncentaHEALTH™ Program) implemented at seven worksites.

The archival records included age and gender assessed at program initiation, retention (three and six months), and weight loss (at three and six months of participation).
in the program). The seven worksites used reflect the total number that had engaged with the commercial program and had all aspects of the archival data available at the time of the study.

All employees who initiated the program were included in the analyses. All archival data was de-identified and program participants had complete anonymity in regards to the research team. Program eligibility criteria included that participants were employed by the worksite and had a BMI greater than or equal to 25.

Briefly, the IncentaHEALTH™ Program included daily e-mail support, access to a comprehensive web site with educational and skill related information, and modest monthly monetary incentives. The monetary incentives were based upon the percentage of body weight lost (e.g., $5/month for 5.0% weight loss), documented at quarterly assessments. The participants were allowed to tailor their diet as per their preferences and also choose between home or gymnasium based exercise program at either a beginner, intermediate or advanced level of exercise. The employer, rather than individual employees, covered the cost of the program.

Participant weight was assessed at baseline, three and six months using a validated and reliable weight scale on site at each workplace. The calibrated scale was accompanied by a built in digital camera that captured an image of the participant during a weigh-in to provide a validity check and for use as motivation (i.e., participants could view progress over time). All worksites provided information on the total number of employees. For the purpose of this study, the unavailability of data on weight at three or six months was used to categorize participants as drop-outs.

To determine the reach of the program into the eligible employee population, simple frequency calculations were used with the total employee population and the total projected eligible population (i.e., 67.0% of US adult population categorized as overweight or obese) as the denominators and the participants engaged as the numerator.

RESULTS
A total of 10,513 people were employed across the worksites (Figure 1) and 4233 eligible employees (BMI =>25) joined the program. The reach of the program into the total population of employees was approximately 40.0%. However when considering the employees that would be eligible for the program, the reach was approximately 60.0%. Sixty six percent of participants were women and the average age was 44.

The mean weight of the participants was 206 (±43.99) pounds and the BMI was 32.4 at baseline. At three months the participants lost a significant amount of weight (t=21.75, p<.001), on average, 2.1 (±6.3) pounds with a 95.0% confidence interval of 1.9 to 2.3 pounds. Similarly, at six months the participants lost a significant amount of weight (t=20.43, p<.001), on average, 2.4 (±7.9) pounds with a 95.0% confidence interval of 2.2 to 2.7 pounds. This weight loss, based on intention to treat analysis, reflected approximately 1.75% of initial body weight lost, on average, by each participant.

It calculated reach by effectiveness of the program by dividing the total number of
participants that lost weight on the program by the total number of employees in the participating worksites. Follow-up analyses were conducted to determine the overall proportion of the workforce that benefited (i.e., lost weight) at six months.

**Figure 1.** Flow diagram of participant recruitment and retention across six months of delivery. Colorado, USA, 2010.

At three months post initiation, 1,928 participants (28.0% of eligible population and 18.0% of total employee population) were retained and at six months, 1,607 participants (23.0% of eligible population and 15.0% of total employee population) were retained on the program. Of the 1,607 participants who were retained at six months, 1,088 were successful in losing weight and lost, on average 9.4 pounds (95.0% CI: 8.8 to 9.9 pounds), a clinically significant 4.4% of initial body weight. Thus, 10.1% of the total employee population and 16.0% of the eligible population benefited from the weight loss program and lost a clinically relevant amount of weight.

**DISCUSSION**

Our primary objective with this paper was to highlight the different ways that reach, retention, and effectiveness data—the same data—could be reported. An overall intent to treat analysis with last assessment carried forward imputation indicated a statistically significant but small weight loss.

Some of the previous studies report a much higher rate of effectiveness\(^{14-16}\), but these studies usually involved high intensity interventions and the final analysis is based on homogenous, highly motivated individuals who are available for final assessments. Those studies provide information with strong internal validity, but from external validity point of view, the samples were unlikely to be representative of participants and settings. Further, seldom do more intensive trials of weight loss interventions present data on the reach into the target population and it may be that there is an inverse relationship between reach and retention.

Intention to treat analysis is considered a scientifically sound means of reporting data on weight loss programs. When we analyzed our data using this method, we found statistically significant, but modest changes in weight, at best. However, when reach, effectiveness and retention data are compiled together, seeing that 10.0% of the overall worksite population benefits at a clinically meaningful level the program seems far more attractive to employers.

Indeed, typical worksite disease
management programs are targeted at diseases with less than a 10.0% prevalence rate. This suggests that this type of worksite weight loss program has a larger impact than most other disease management approaches. Clearly, different methods of presenting the same data can lead to very different conclusions about a program. Using reach, retention, and effectiveness data provides a richer source of information to truly indicate what proportion of an employee population will benefit, and to what degree.

Nevertheless, there are a number of limitations to our approach. First, since this was a pilot study using archival records, no control group was used. Hence, there was limited ability to measure individual changes and whether the program prompted these behavior changes. As we used archival data from a commercial weight loss program we also have no additional information on demographics of the participants to determine representativeness.

CONCLUSION

Worksite health professionals are faced with numerous decisions related to health promotion programs that will be offered to their workforce. However, most studies do not report or control for attrition rates, making the effectiveness data reported, only the best case scenario.

The method reported in this paper, could serve as a template for commercial and research programs to document the proportion of the employees that ultimately benefit from a wellness program and the degree to which that benefit is clinically meaningful.

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CONTRIBUTIONS
Paul Andrew Estabrooks conceptualized the study, participated in the study design, contributed to data analyses, participated in the interpretation of results, and led the manuscript writing;
Mita Shah Bhagat participated in the study design, collected the data; and contributed to the manuscript drafts;
Fabio Araújo Almeida participated in the study design and interpretation of results, and contributed to the manuscript drafts;
Brenda Marie Davy participated in the study design and interpretation of results and contributed to the manuscript drafts;
Wendy You led data analyses, participated in the interpretation of results, participated in the study design and contributed to the manuscript drafts.