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Predicting dropout in dietary weight loss trials using demographic and early weight change characteristics: implications for trial design

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Abstract

Summary Attrition causes analytical and efficacy issues in weight loss trials. Consistent predictors of attrition in weight loss trials have not been identified. Trial design could be improved if factors predicting attrition are accounted for. The aim of this study is to quantify the effect of easily measured pre study and early study variables to determine their relationship with attrition in dietary weight loss trials. Methods Data was pooled from four previous dietary weight loss trials. Mixed effects logistic regression, Receiver Operator Curves and decision trees (classification and regression trees) were used to determine which of the variables (percent weight loss at 1 month, age, gender and baseline BMI) predicted dropout and to determine cutoffs useful for future trial design. Results The sample included 289 subjects, 73% female, with a mean age of 46.68 ± 9.27 years and average dropout of 25%. Percent weight loss at 1 month was the strongest predictor of dropout, those with a weight loss ≤2% were 4.99 times (95% CI 2.71, 9.18) more likely to drop out than those with a weight loss >2% in the first month ($P < 0.001$). When considering only data available at the beginning of a trial those ≤50 years old were 2.07 times (95% CI 1.2, 3.5) more likely to drop out than those >50 ($P = 0.006$). Discussion Early weight loss and age were identified as significant variables for predicting attrition in weight loss trials. Trial designs maybe improved by incorporating these variables and developing interventions targeting these factors may improve participant retention.

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Predicting dropout in dietary weight loss trials using demographic and early weight change characteristics: Implications for trial design.

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Keywords: obesity, attrition, dietary intervention

Abstract

Attrition causes analytical and efficacy issues in weight loss trials. Consistent predictors of attrition in weight loss trials have not been identified. Trial design could be improved if factors predicting attrition are accounted for. The aim of this study is to quantify the effect of easily measured pre study and early study variables to determine their relationship with attrition in dietary weight loss trials.

Methods

Data was pooled from four previous dietary weight loss trials. Mixed effects logistic regression, Receiver Operator Curves and decision trees (classification and regression trees) were used to determine which of the variables (percent weight loss at 1 month, age, gender and baseline BMI) predicted dropout and to determine cutoffs useful for future trial design.

Results

The sample included 289 subjects, 73% female, with a mean age of 46.68±9.27years and average dropout of 25%. Percent weight loss at 1 month was the strongest predictor of dropout, those with a weight loss ≤2% were 4.99 times (95%CI 2.71,9.18) more likely to drop out than those with a weight loss > 2 % in the first month (P<0.001). When considering only data available at the beginning of a trial those ≤ to 50 years old were 2.07 times (95%CI 1.2,3.5) more likely to drop out than those > 50 (P=0.006).

Discussion

Early weight loss and age were identified as significant variables for predicting attrition in weight loss trials. Trial designs maybe improved by incorporating these variables and developing interventions targeting these factors may improve participant retention.

Introduction

Study attrition or drop out raises major analytical and efficacy issues in weight management trials[1]. Determining predictors of attrition is crucial for appropriately designing weight loss interventions and the subsequent design features to test their effect. A systematic review considered demographic and psychological factors and their relationship with attrition[2], consistent factors were not identified.

The aim of this research is to consider simple demographic variables collected prior to study commencement and initial weight loss and their role in predicting dropout in dietary based weight loss studies. Quantifying these variables would assist with study design in establishing criteria for stratification and randomisation.

Methods

This study was a pooled analysis of 4 previously published studies[3-6]. All studies were registered (www.anzctr.org.au ACTRN12608000425392, ACTRN12610000784011, ACTRN12608000453381, ACTRN12606000530527). Studies one and two were one year studies, the first involved a treatment arm focussing on increasing vegetable intake compared with standard dietary advice based on the Australian Guide to Healthy Eating[3]. The second study again had a control arm based on the Australian Guide to Healthy Eating. The treatment arms in this study involved increasing fish intake alone or in combination with a supplement to increase the amount of long chain n3 polyunsaturated fatty acids[4]. Studies three and four were 12 weeks studies, study 3 compared diets high in protein from meat or soy sources to a low fat control and study 4 had 4 arms comparing an isocaloric low fat, isocaloric with 10% polyunsaturated fatty acids, low calorie low fat and low calorie with 10% PUFA. All trials had similar inclusion criteria which included BMI 25-35kg/m^2 and age 18-65 years[3] for study one, or BMI 25-37kg/m^2, age 18-60 years for study 2 and 3[4, 5], and

BMI>25kg/m^2 and age >18 years for study 4[6]. Exclusion criteria for all studies included major illnesses (such as cancer), chronic diseases such as diabetes or voluntary weight loss proceeding the study period. Those participants who unwilling to comply with the specific dietary interventions were also excluded prior to randomisation. In addition those with LDL≥6mmol/l and those taking fish oil supplements in the last 12 weeks were excluded from study 2[4]. Institutional ethics approval was granted for all initial studies and for this pooled analysis. Data extracted from the studies included the weight at 1, 3 and then 12 months for studies 1 and 2, baseline BMI, age, gender, and dropout (attrition) was also recorded.

Data analysis

Baseline characteristics for the four study samples were summarised using descriptive statistics and compared using one way ANOVA for continuous variables with post hoc comparisons using Bonferroni adjustment. The Pearson Chi Square statistic was used to compare proportions, post hoc comparisons were conducted using Bonferroni adjusted z tests for comparing columns.

Characteristics predicting attrition were modelled, adjusting for clustering within study, using generalised linear models. Initially percent weight loss, age and BMI were compared as continuous variables. XTMELOGIT in STATA (V 12 Cary, NC) was used to perform the cluster mixed effects logistic regression, where study was considered a random effect. Models were compared using the likelihood ratio test. While logistic regression presents an odds of dropout which is useful in describing the importance of independent variables in predicting the outcome, in the clinical context a decision tree approach is a more useful visual method for presenting results. Various decision based analyses exist in the literature (Chapter 9[7]) including discriminant analysis and signal detection analysis. Discriminant analysis is largely surpassed by logistic regression due to less restrictive modelling assumptions and software options are limited for signal detection analysis. Decision trees are available in most commercial software packages are easy to interpret, in this analysis the Classification and Regression Tree procedure ([8], Chapter 9 in[7]) was used (SPSS V21, IBM Inc, Armonk NY). This procedure was used to determine the predictors of dropout and to develop cutpoints. These cutpoints were then verified using undjusted Receiver Operating Curves, sensitivity and specificity by modeling different cutoffs of weight loss at one month and age for predicting attrition. Increments of 0.5% for weight loss and one year and the sample quartiles for age were considered. ROCREG in STATA was used adjusting for ties. The criteria were compared using the wald statistic. The criteria used to assess the best cutoff were the AUC, clinical relevance and the wald statistic for comparing models. These cutoff criteria were then used in additional mixed effect logistic regression models to provide odds ratios adjusted for clustering due to study.

Results

One month weights were routinely recorded for studies 1-3. For study 4 weight was only recorded at month 1 for a subset of participants. The final analysis contained 289 subjects who had a weight recorded at 1 month. Demographic details of the subjects included from the studies are shown in Table 1. Dropout varied between the parent studies and the subsets reported here (Table 1).

Table 1. Summary statistics of the samples from the four studies

Variable	Study 1[3]	Study 2[4]	Study 3[5]	Study 4[6]	overall	*P*
M/F	28/84	27/80	14/27	10/19		0.525
Weight baseline	84.78±11.60 [a]	88.72±11.60 [ab]	91.52±14.30 [b]	89.00±13.30 [ab]	87.62±12.37	0.010
BMI baseline	29.98±2.74 [a]	31.18±3.41[b]	32.24±3.28[b]	31.75±3.70[b]	30.92±3.27	<0.001
Age	49.00±9.41 [a]	44.96±8.53[b]	46.20±8.66 [ab]	44.76±10.79 [ab]	46.68±9.27	0.007
% weight loss 1 month	-2.60±2.16	-2.66±1.88	-2.71±1.93	-2.74±2.37	-2.65±2.04	0.984
% weight loss 3 months	-5.29±3.45	-5.31±3.48	-6.02±3.86	-5.21±3.56	-5.39±3.52	0.969
% weight loss 12 months	-7.46±5.68	-7.18±5.15	NA	NA	-7.35±5.46	0.753
Dropout	19/112(17%)[a]	44/107(41%)[b]	6/41(15%)[a]	2/27(7%)[a]	71/289(25%)	<0.001

[ab]Groups with different subscripts are significantly different (P<0.05) using Bonferroni adjusted z tests for comparing columns.

Treatment was initially considered in the models, there was no significant effect (P=0.654 in model with initial weight loss and P=0.555 in model without initial weight loss) and so this variable was not considered further. Three of the four studies demonstrated no difference in the amount of weight loss at the end of the study between treatment and control groups.

Table 2 shows the results of the mixed effects logistic regression. Models 1 shows the entry model for percent weight loss at 1 month as a continuous variable with age, BMI and gender. Using the likelihood ratio test removing any of the variables (age, BMI, gender) in a backward stepwise method did not improve the model fit (P=0.095-0.345) and therefore the full model was retained. Removing percent weight loss from the model allowed use of criteria to determine predictors of attrition at study entry. The logistic regression model including age, BMI and gender showed that only age was significant (model 2) removing BMI or gender did not improve the model (χ^2=1.47 df(1)P=0.225 BMI and χ^2=2.83 df(1)P=0.093, removing BMI and gender χ^2=2.83 df(2)P=0.145) using the likelihood ratio test.

Table 2. Multivariate mixed effects logistic regression models for predicting dropout.

Models	Odds ratio	CI	z	P
1. % weight loss continuous				
% weight loss 1 month	1.27	(1.09,1.48)	3.10	0.002
Age	0.98	(0.95,1.01)	-1.44	0.151
BMI	1.04	(0.96,1.14)	0.94	0.347
gender	1.78	(0.89,3.57)	1.63	0.104
2. pre study variables continuous full				
Age	0.98	(0.95,0.999)	-2.05	0.041
BMI	1.04	(0.98,1.11)	1.21	0.225
Gender	1.55	(0.92,2.64)	1.65	0.098
3. weight loss ≤ 2% binary				
weight loss ≤ 2%	5.32	(2.85,9.94)	5.25	<0.001
Age ≤ 50 years	1.96	(0.98,3.90)	1.92	0.055
BMI	1.05	(0.95,1.15)	0.95	0.342
Gender	1.74	(0.92,3.91)	1.74	0.081
4. weight loss ≤2% binary				
weight loss ≤2%	4.99	(2.71,9.18)	5.17	<0.001
5. pre study variable age ≤ 50 years binary				
Age ≤ 50 years	2.07	(1.23,3.47)	2.74	0.006
BMI	1.04	(0.97,1.11)	1.18	0.236
Gender	1.50	(0.88,2.54)	1.50	0.134

The classification and regression tree procedure selected only percent weight loss at 1 month as the only predictor variable with a split at 1.992% weight loss (rounded to 2% for ease of application), see Figure 1. To verify these results we considered the proportion of participants losing weight at 0.5% increments from baseline increments starting with 0.5 to 5%. The AUC and associated CIs are shown in Table 3. The overall wald test that the AUC were equal was significant P<0.001 indicating at least one classifier was significantly different. As the cutoff at 2% had the highest AUC the only post hoc tests considered to reduce the risk of type 1 error were whether this cutoff was significantly different to those immediately surrounding this criteria, the 1.5% (P=0.0174) and the 2.5% (P=0.0004) cutoffs. Logistic regression for percent weight loss at 1 month as a continuous variable indicates that for every 1% reduction in the amount of weight loss the risk of dropping out increases by 1.27 times (model 1). When percent weight loss at one month and age were considered as binary variables, only weight loss ≤2% was significant in the entry model with those with a weight loss ≤2% being 5.32 (2.85,9.94) times more likely to drop out than those with a weight loss > 2 % in the first month (Model 3). Again removing age, BMI, or gender from the model did not improve the model fit (P>0.05), however removing all three did improve the model (χ^2=8.37,df=3,P=0.039), indicating that weight loss ≤2% was the strongest predictor of attrition (model 4). In this model participants with a weight loss ≤2% were 4.99 (2.71,9.18) times more likely to drop out and those with a weight loss >2%, a finding consistent with the decision tree.

Figure 1 Decision tree for predicting drop out with % percent weight loss, age, BMI and gender.

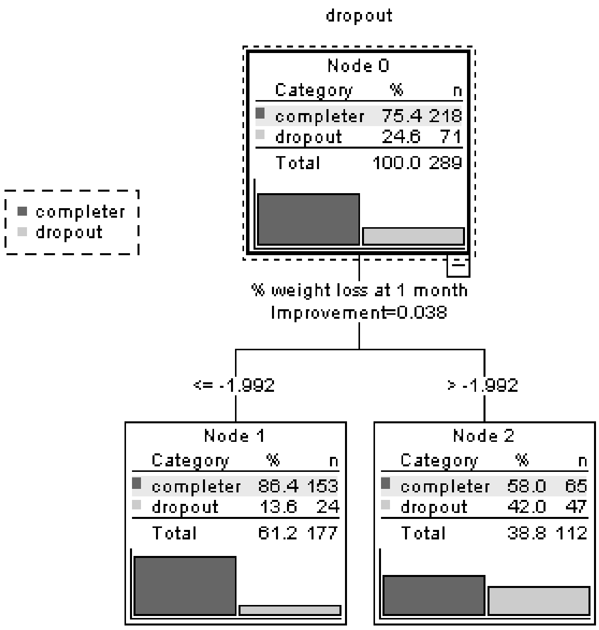
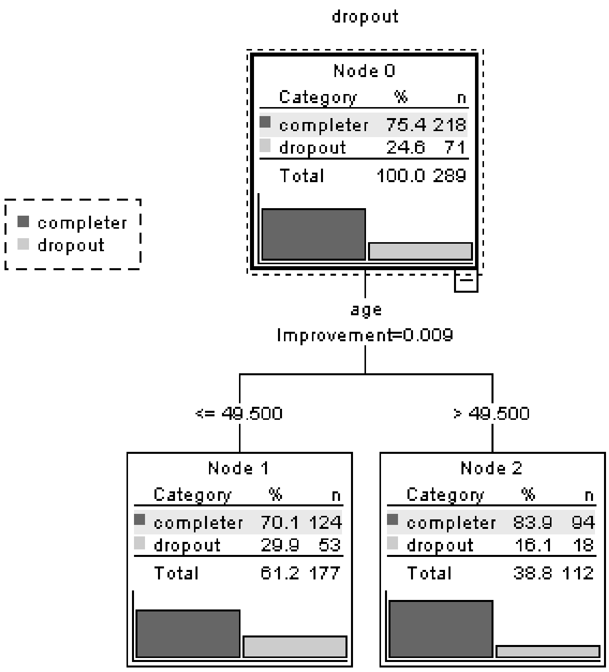


Table 3. Area under the curve, sensitivity and specificity for predicting dropout using incremental changes in percent weight loss and Age.

	AUC	CI	Sensitivity(%)	Specificity(%)
1. % weight loss criteria				
0.5%	0.535	(0.478,0.593)	18.31	90.37
1.0%	0.564	(0.496,0.633)	30.99	84.40
1.5%	0.604	(0.532,0.677)	45.07	78.90
2.0%	**0.658**	**(0.589,0.727)**	**66.20**	**69.72**
2.5%	0.598	(0.528,0.667)	67.61	59.63
3.0%	0.573	(0.513,0.633)	76.06	49.08
3.5%	0.523	(0.476,0.571)	81.69	37.16
4.0%	0.523	(0.476,0.571)	83.10	25.23
4.5%	0.523	(0.476,0.571)	85.29	22.16
5.0%	0.523	(0.476,0.571)	89.39	13.30
2. Age criteria				
46	0.574	(0.521,0.628)	60.68	54.20
47	0.578	(0.525,0.630)	64.10	51.40
48	0.563	(0.511,0.616)	65.81	46.85
49	0.591	(0.542,0.640)	75.21	43.01
50	**0.589**	**(0.542,0.636)**	**78.63**	**39.16**
51	0.574	(0.529,0.620)	80.34	34.62

When percent weight loss at 1 month was removed from the model to consider only those variables available pre study commencement, the decision tree model selected only age as a predictor of dropout based on a cutoff of 49.5 years (Figure 2). Using this value and the sample median (46) ages of 46 through to 51 were considered using the ROC curve. The AUC, sensitivity and specificity produced the best values at an age of 49 and 50 with no significant difference between the values considered P=0.135, or by considering age 49 to age 50 as a post hoc test P=0.824 (Table 3). For ease of application the value of 50 years was used in the categorical logistic regression (Model 5). Again age, BMI and gender were considered, in the entry model only age was significant however removing BMI and gender did not improve the model fit (removing BMI χ^2=1.40 df(1)P=0.236, removing BMI and gender χ^2=3.30 df(2)P=0.192). Logistic regression with age as a continuous variable (model 2) indicates that for every one year increase in age the odds of dropping out decrease by 2.5%. When considered as a categorical variable (model 5) those less than or equal to 50 years old were two times (1.2,3.5) more likely to drop out than those older than 50, P=0.006.

Figure 2 Decision tree for predicting drop out with age, BMI and gender.



Discussion

The aim of this analysis was to demonstrate whether readily available demographic and early trial success information could be used to predict attrition in dietary weight loss trials. Two statistically significant and relevant models were considered. The first model demonstrated that greater than or equal to 2% weight loss in the first month of the study was the most significant predictor of dropout and could be used independently to predict attrition. Considering that this variable occurs after trial commencement we considered a second model using only age, BMI and gender to determine if these characteristics predict attrition. Age was the strongest predictor however there was variation between the two modelling procedures suggesting that further investigation of the role of BMI and gender in predicting dropout is warranted. Our results suggest all 3 variables should be considered in randomisation of patients to treatment arms. Given the strong impact of 1 month weight loss on predicting dropout, designs which take this initial weight loss into account are recommended.

Several researchers have previously demonstrated that initial weight loss is associated with study dropout in dietary based weight loss trials[9-16], however this finding is not consistent and others have found no relationship[11, 17, 18]. This is the first study to quantify the amount of initial weight loss which predicts dropout and to investigate and quantify additional easily obtainable subject characteristics such as age which can be used to ensure adequate randomisation.

Age was considered as a variable predicting attrition in 33 studies in the review conducted by Moroshko and colleagues with 17 studies finding no relationship, 13 showing an association with younger age, 1 study showing an association with younger age in women and not men and only 2 small studies finding dropout associated with older age[2]. Since the publication of this review a further study has supported the relationship between attrition and younger age[15], with a further four studies showing no relationship[9, 17-19]. A recent pooled analysis of individual patient data from 10 large obesity RCTs in the US showed a significantly increased risk of dropout with advancing age (HR 1.02, 95% CI 1.01,1.02)[20] however weight loss was not the primary outcome in most of these studies therefore it is possible that the subjects in these studies differ from those in studies focussed primarily on weight loss, the dropout rates were low (3.7-17.2%) compared with the averages reported in previous research (23%, 26.3%)[21, 22] and the range in the systematic review (7-90%)[2]. It is also important to consider that these papers generally represent secondary, unplanned, post hoc analyses and particularly with respect to the papers showing no effect there is a high risk of type 2 error, that is the studies have insufficient power to demonstrate a significant effect. In view of this limitation and the different study outcomes in the recent pooled analysis it is reasonable to suggest that younger age predicts attrition in weight loss studies. The current research quantifies this difference suggesting that those participants younger than 50 years are at greater risk of attrition than those 50 and older.

The consideration that analyses investigating attrition are generally post hoc and unplanned also makes the relationship between attrition and gender and attrition and initial weight or BMI unclear as the majority of studies show no relationship[2, 15, 19]. Where a relationship does exist it appears that females may be more likely to drop out than males[2], although a more recent study has shown that males are more likely to drop out than females[23]. The 2011 systematic review found roughly equal (but small n=4-5) numbers of papers supporting a relationship between high or low initial weight and attrition compared with 18 reporting no relationship more recent papers continue to differ with some supporting the relationship between higher initial weight [18, 20]and attrition and some lower initial weight[15] (although no relationship is still the most frequent[9, 17, 19]).

Behavioural and psychological characteristics have been shown to be associated with trial dropout in previous research, although reporting is inconsistent and methodology differs[2]. We support the view of others[2, 15] that these factors should be the focus of the interventions administered in the weight loss trials and should be measured to determine ways of improving the retention rates in dietary and lifestyle related weight loss trials. The focus of this paper however is on factors associated with the initial trial design. Measuring initial weight change is an easy and consistent way to identify potential attrition in weight loss trials. One month was the earliest time point at which weight was recorded in the weight loss trials studied here. Recent research has demonstrated that weight loss as early as one week[16] or BMI changes as early as two weeks may be predictive of dropout[10] and future research should investigate the role of weekly monitoring to quantify the risk of dropout.

This research highlights two particular variables, initial weight loss and age, which were predictive of attrition in our study samples. The trials considered here recruited subjects with similar demographic characteristics and the particular cutoffs relevant for our studies may not be relevant for other study populations. For example the NUGENOB study[16] only recruited subjects between 20-50 years of age and therefore different age stratification was warranted. The intention of this analysis is to raise awareness of the need to consider different study populations and design interventions incorporating known potential covariates that may predict attrition in the relevant demographic group. The variables considered in this analysis, particularly initial weight loss are also associated with predicting the amount of weight lost (success) in obesity management trials and although this was beyond the scope of the current analysis, several papers have reported this[16, 23-25].

Further implications of this analysis are that weight loss trial designs should be investigated where an initial treatment period common to all participants is introduced followed by stratification based on weight loss in the initial weeks or months of the study. As the amount of the weight loss in the first month was independent of treatment assignment in this analysis it is possible that this initial response is related more to participant characteristics than treatment effects. New design methods such as sequential multiple assignment should be considered where the initial response is part of the study design[26]. Here all participants are randomised at least once, however those who fail to respond at a predefined time point are further randomised into more than one treatment option. Adaptive designs where randomisation of incoming subjects in based on the early weight loss of existing subjects could also be considered[27]. The potential for the use of these designs in weight loss, sample size estimation and analysis is covered in detail in Almirall et al[26]. In these designs specific strategies could be implemented for those not responding in the initial phase and this difference in initial response can then be modelled appropriately in the analysis.

There were some limitations to this study. Other variables which are routinely collected at study entry could also be considered in models predicting dropout. Education level and occupation have also been shown to be associated with attrition, this information was not collected for all subjects in the study and the inclusion of these variables reduced the size of the dataset. Given that some studies have shown relationships with BMI and gender and attrition[2], it may be the case that our sample size was inadequate to demonstrate these relationships, particularly given the range of significance for gender was P=0.081-0.134 in the models. Further research should be done on larger studies and pooled datasets to definitively investigate these relationships and to determine if higher sensitivity and specificity can be obtained. Data on the one month weight loss was also not available for all subjects and it would certainly be a recommendation of this research that early weight change information should be routinely collected in all weight loss studies given the strong association shown in this and other studies with both attrition and weight loss success.

In conclusion demographic variables such as age should be routinely used to stratify patients on study entry, while the role of gender and BMI were less apparent in this study it would be prudent to consider these in the randomisation as well. Early weight changes in the initial part of weight loss interventions should be incorporated in the design process.

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