Evaluating disease management programme effectiveness: an introduction to the regression discontinuity design

Ariel Linden DrPH MS,[1] John L. Adams PhD[2] and Nancy Roberts MPH[3]
[1]President, Linden Consulting Group, Portland, OR, USA
[2]Senior Statistician, RAND Corporation, Santa Monica, CA, USA
[3]Regional Director of Integrated Performance/Six Sigma Champion, Providence Health System, Portland, OR, USA

Correspondence
Ariel Linden
Linden Consulting Group
6208 NE Chestnut Street
Hillsboro
OR 97124
USA
E-mail: ariellinden@yahoo.com

Keywords: cut-off point, disease management, evaluation, observational study designs, regression discontinuity

Accepted for publication:
10 September 2004

Abstract

Although disease management (DM) has been in existence for over a decade, there is still much uncertainty as to its effectiveness in improving health status and reducing medical cost. The main reason is that most programme evaluations typically follow weak observational study designs that are subject to bias, most notably selection bias and regression to the mean. The regression discontinuity (RD) design may be the best alternative to randomized studies for evaluating DM programme effectiveness. The most crucial element of the RD design is its use of a 'cut-off' score on a pre-test measure to determine assignment to intervention or control. A valuable feature of this technique is that the pre-test measure does not have to be the same as the outcome measure, thus maximizing the programme's ability to use research-based practice guidelines, survey instruments and other tools to identify those individuals in greatest need of the programme intervention. Similarly, the cut-off score can be based on clinical understanding of the disease process, empirically derived, or resource-based. In the RD design, programme effectiveness is determined by a change in the pre–post relationship at the cut-off point. While the RD design is uniquely suitable for DM programme evaluation, its success will depend, in large part, on fundamental changes being made in the way DM programmes identify and assign individuals to the programme intervention.

Introduction

Disease management (DM), as defined by the Disease Management Association of America (2004), is a system of co-ordinated interventions and communications for populations with conditions in which patient self-care efforts are significant. Disease management programmes were developed under the assumption that by augmenting the traditional episodic medical care system with services and support between doctor visits, the overall cost of health care could be reduced. For many chronic diseases, such as diabetes, asthma, and congestive heart failure, there is much opportunity to improve the quality and consistency of care. Disease management programmes were developed to assist doctors and their patients in identifying and closing those gaps in care.

Although DM has been in existence for over a decade, there is still much uncertainty as to its effectiveness in improving health status and reducing medical cost. While the randomized controlled trial (RCT) is widely regarded as the 'gold standard' of research designs, there are logistic, practical and ethical limitations that preclude its use in evaluating DM programme effectiveness. First, DM programmes typically contend that the impact of the

intervention can be experienced at the population level via the 'diffusion effect' onto non-participating members from broad exposure to advertising campaigns and the encouragement of their doctors who may have other patients participating successfully in the programme. As a result, this may limit the ability to find a suitable number of programme-free control group subjects. Second, RCTs are frequently limited in their generalizability across persons, settings, treatments and outcomes, as they are often implemented on a highly selective group of individuals (Linden *et al*. 2004a). Finally, with the underlying assumption that DM interventions are effective in improving health status, there is the ethical dilemma of withholding treatment from suitable programme candidates.

Nearly all DM programmes follow some version of a pre–post study design without a control group and actively pursue enrolment of those members who are the sickest, or at highest risk (Linden *et al*. 2003a). In addition, individuals can self-select into the programme as long as they meet the inclusion criteria. A complication of these two factors is that selection bias and regression to the mean become the two biases that most cloud the interpretation of DM programme outcomes using pre–post evaluation techniques (Linden *et al*. 2003b).

While it is typically unfamiliar to those outside the research community, the regression discontinuity (RD) design may be the most suitable alternative to randomized studies in DM programme evaluation. While the first published application of the RD design was in 1960 by Thistlethwaite & Campbell (1960), it has since been refined to the approach currently in use (Trochim 1984, 1990). That said, there is little evidence of its inclusion in the health services research literature, although it has been proposed as a suitable technique for use in the public health domain (Finkelstein *et al*. 1996a). As the name implies, the defining characteristic of the RD design is in identifying whether a discontinuity in the relationship between the assignment variable and outcome occurs at the point differentiating the treatment and non-treatment groups (Luft 1990). As opposed to the RCT in which individuals are randomly assigned to treatment or control group, the RD design utilizes a 'cut-off' score on a pre-programme measure or test, to determine who will be assigned to the intervention or used as a control. This cut-off mechanism is what makes the RD design so uniquely suitable for DM programme evaluations. Differences in participation selection (which typically plagues the validity of most observational studies) are actually required in the RD design. Similarly, regression to the mean (RTM) and other typical biases are discounted as threats to validity because they would have to be demonstrated exactly at the cut-off point, which is a highly unlikely scenario in DM.

This paper introduces the RD design as an alternative, and more appropriate, approach to evaluating DM programme effectiveness than the currently used pre–post design with no control group. Model development and discussion will be provided so that these techniques can be easily replicated in DM programme evaluations. For those organizations that purchase DM services, this paper will provide a substantive background with which to discuss the RD design as an alternative evaluation possibility with their contracted vendors.

Elements of the regression discontinuity design

Choice of pre-test measures

Most, if not all, current DM programme evaluations compare costs and health service utilization in the year prior to programme implementation to those same measures at the end of each programme year, with the difference between the two indicating whether the programme was successful or not. A valuable feature of the RD design is that the baseline measure does not have to be the same as the outcome measure, thus maximizing the programme's ability to use research-based practice guidelines, survey instruments and other tools to identify those individuals in greatest need and then assign them to the intervention.

For example, nearly all chronic illnesses have some clinical measure of a patient's disease burden. In coronary heart disease these include: blood pressure, cholesterol and lipid levels, etc. In diabetes, measures include: HbA1c and blood glucose levels. In congestive heart failure (CHF), the measure of choice is the ejection fraction, while in asthma it may be peak flow, or forced expiratory volume (FEV1). There are also

many general and disease-specific survey tools that have been validated for use in identifying health status, functional status, quality of life, etc. for individuals and populations (McDowel & Newell 1996) that are uniquely suited as a baseline measure of programme need. Predictive modelling offers another scalar function that can be used to optimize the identification of programme suitable individuals and assign them to the intervention (Cousins *et al*. 2002). A composite score comprised of results from different tools, surveys, and/or models can also be constructed for use as the baseline measurement. This composite, however, must ensure reliable results given the different weighting schemes and scoring mechanisms of each tool separately.

While the pre-test measure does not have to be identical to the outcome measure, or for that matter even correlated with it (Reichardt *et al*. 1995), the pre-test measure does have to be on either a continuous or ordinal scale. As clinical measures, survey results, predictive model scores, and even economic markers are typically continuous variables, this rule is easy enough to satisfy.

The cut-off score

The strength of the RD design resides in its use of a cut-off score on the pre-test measure for assigning suitable individuals to the programme intervention. The cut-off score can be based on clinical understanding of the disease process, empirically derived (e.g. percentile ranking), or resource-based (e.g. available resources needed to manage a given population size).

Clinically meaningful threshold values may prove to be the most useful of cut-off scores because they will have already been identified as being valid indicators of disease risk and are more likely to achieve general acceptance from the medical community. Using some examples from the previous section, cut-off scores can be set either to accepted normal levels or to specific upper-bounds such as 200 or 240 mg dL^{-1} for total cholesterol, 120/80 or 140/90 mmHg for blood pressure and 7.0 or 8.5% for HbA1c values.

Cut-off scores can also be empirically determined. Statistical power and the estimation of interactions are both facilitated if the cut-off is the mean of the distribution of assignment variable scores (Shadish *et al*. 2002). Therefore DM programmes may initially choose to rely on their experience across different suitable populations to determine the distribution and hence the cut-off.

When programme resources limit the enrolment to a given number of participants the cut-off may be set to enrol those members with greatest need. For example, if using a health risk appraisal as the pre-test measure (which typically scores on a scale from 0.0 to 1.0 with higher values indicating higher risk), the cut-off can be moved down the scale until the desired number of suitable high risk members are identified.

Multiple cut-off points can be used for those DM programmes that have a tiered intervention. For example, if a programme uses a pre-test continuous measure (scaled from 1 to 100), has a nursing intervention for the high-risk participants, and has a mail correspondence programme for the intermediate-risk members, hypothetical cut-offs could be set at 80 for the high-risk group and 50 for the intermediate-risk group, with anyone scoring below that assigned to the control group.

With the cut-off score being so integral to the RD design as a means of assigning individuals to the intervention, DM programmes choosing to adopt this method will have to embrace this philosophy in lieu of present identification algorithms. Currently, most programmes classify individuals as high-risk (and thus suitable for the intervention) if they were identified via claims data as having either a hospitalization or emergency department (ED) visit within the past year. Because of its binary nature this method is not consistent with the requirements of the RD design.

Choice of outcome measures

To interpret the results from an RD analysis one needs to understand the fundamental relationship between the pre-test measure and outcome. This is a somewhat novel concept in the DM industry where associations between pre-test, intervention and outcome are tenuous at best. For example, the present DM model typically uses baseline costs as the pre-test, intervenes on a member to improve disease self-management techniques, and measures costs again as

the outcome. Is it reasonable to assume that changing health-related behaviours will result in lowered costs within 1 year? Moreover, is it reasonable to assume that changes in costs are somehow associated with illness severity? A more suitable design would assess the individual's illness burden, or their readiness to change health-related behaviours (Linden & Roberts 2004) at baseline, focus the intervention on those specific variables that are expected to be impacted, and then measure the impact on those variables at post-test. The degree to which an individual manages their disease process (e.g. adherence to the treatment regimen) or their change in illness burden or quality of life is a more sensitive measure of the impact of a DM programme intervention – at least in the short run. Therefore, the higher the correlation between the pre-test and post-test measure, the more precise will be the estimate of the main effect of the DM intervention (Reichardt *et al*. 1995). In contrast to the pre-test measure, the outcome variable does not have to be on a continuous scale. The model will work equally as well with either dichotomous or ordinal measures.

Visual display and interpretation of regression discontinuity results

Visual inspection of the data will, in most cases, provide a clue as to the form that the RD design will take. The approach is to chart the data for each group using a scatterplot. Most basic computer programs having graphing capabilities can also provide a trend line. Figure 1a–c illustrates several possible results of an RD analysis. In this hypothetical example, all individuals are assigned to treatment or control based on the pre-test cut-off score of 50. At the end of the evaluation period, they receive the post-test, which in this example is on the same scale as the pre-test (1–100). Figure 1a illustrates a case in which there is no treatment effect. This is evidenced by the regression line that runs straight through the data-points on both sides of the cut-off, indicating a positive correlation between the pre-test and post-test across the entire spectrum of scores. Therefore, the interpretation of these results suggests that individuals will score similarly on both the pre-test and post-test, regardless of whether they were assigned to treatment or control.

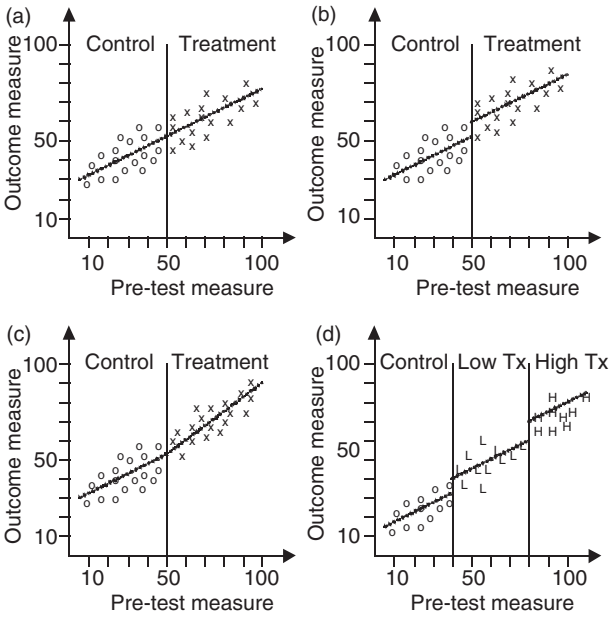

Figure 1 Graphic display of the regression discontinuity design. Individuals are assigned to treatment or control group based on their pre-test measure cut-off score (vertical line). Regression lines are fitted to each group's data (dotted lines): (a) shows no treatment effect, (b) shows a classic discontinuity, indicating a treatment effect in the level, (c) shows curvilinear relationship but no treatment effect, and (d) shows a treatment effect at multiple cut-off scores. Tx, treatment.

Figure 1b demonstrates the classic RD design. In this scenario the treatment shows a positive effect, as indicated by the 'discontinuity' of the regression line at the cut-off point. As illustrated, the treatment group scored consistently 10 points higher on their post-test than did the controls.

Figure 1c illustrates an RD in the *slope* of the regression line on the treatment side of the cut-off (in contrast to the discontinuity in the *level* shown in Fig. 1b). In this scenario a curvilinear relationship is exhibited, but the treatment shows no effect at the cut-off.

Figure 1d portrays a situation in which there are two levels of an intervention (low treatment and high treatment) together with a control group. As illustrated, there is a treatment effect at the cut-off point between the control group and the low treatment group, and then again at the cut-off point between the low and high treatment groups. Therefore, on visual inspection it appears that the low treatment

was more effective than the control, and the high treatment was more effective than the low.

Although not illustrated here, it is also quite possible that an RD outcome will be indicated by a change in both the level and slope of the regression line on the treatment side of the cut-off. Similarly, as outcomes may follow a non-linear trend, it is imperative that the appropriate statistical models be used to assess and capture that possibility.

While visual inspection of the data and graphic displays provide a general idea as to the structural form of the RD model, statistical modelling must be performed to verify whether the discontinuity is indeed statistically significant. For readers interested in the actual statistical analysis, Appendix 1 provides a comprehensive discussion of the modelling procedure.

Validity of the regression discontinuity design

Several studies have provided statistical evidence that the RD design imparts unbiased estimates of a treatment effect (Rubin 1977; Cappelleri *et al*. 1991; Reichardt *et al*. 1995). Additionally it has been demonstrated that when using the same data set, the RD design achieves similar results to that of the RCT (Finkelstein *et al*. 1996b). The principal feature of the RD design – the cut-off point – is what allows this method to avoid threats to validity that other quasi-experimental designs are susceptible to.

Selection bias

A fundamental criterion necessary for obtaining an unbiased estimate of a treatment effect is to have an assignment process that is completely known and perfectly measured (Shadish *et al*. 2002). Many observational study designs are biased by how individuals are selected for participation in the study or control group. Upon reviewing the difference in outcomes between the two groups it may be difficult to determine whether the intervention was effective or whether the results were a function of this selection bias. In the RD design, however, programme effectiveness is determined by a change in the pre–post relationship at the cut-off point. Therefore, any such selection bias must produce a discontinuity that occurs distinctly at the cut-off point for it to be considered a true threat to the validity of the study findings, a situation highly unlikely in all evaluation settings DM included (Trochim 1984, 1990).

Regression to the mean

Some amount of RTM is expected to occur naturally. As shown in Fig. 2, if RTM does exist in the RD design, it will be captured in the regression line causing the trend to become more horizontal across the spectrum of pre-test values. As illustrated in this single health plan example (using a continuously enrolled cohort over the course of 2 years during which no chronic disease interventions were in place), regardless of type of chronic illness, the RTM pattern is similar (Linden *et al*. 2003a). Given this uniformity, we would not expect to observe a discontinuity coinciding with the cut-off point (Trochim 1984, 1990).

Maturation

Maturation – a scenario in which the outcome is naturally improving for those in the intervention faster than those in the control (Shadish *et al*. 2002) – may be a plausible bias in long-term follow-up studies (Høglend 1996). This would appear as a curvilinear trend through that group's data points, but the appropriate modelling procedures would identify and control for it (Shadish *et al*. 2002).

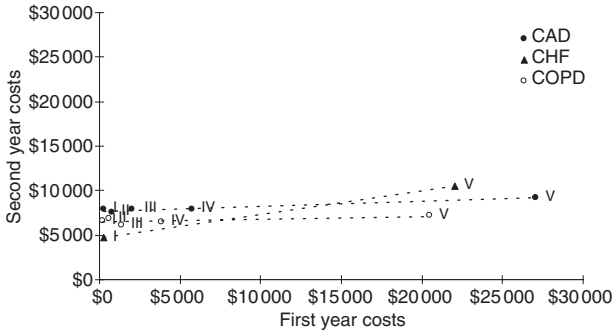

Figure 2 Actual data illustrating the regression to the mean phenomenon in coronary artery disease (CAD), congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD). Quintiles are ranked from I to V, with I being the lowest cost group and V being the highest. All patients were continuously enrolled during the 2-year period.

External validity

Similar to the RCT, the RD design does not ensure external validity. As most programmes are implemented in a particular setting with a given set of individuals under a specific set of circumstances, the results may be limited in their generalizability across persons, settings, treatments and outcomes. Therefore, to increase the generalizability potential of the study outcomes, the programme intervention must be as inclusive as possible across as many domains as feasible (Linden *et al*. 2004a).

Requirements for using the regression discontinuity design

Trochim (1984, 1990) suggests that there are five key assumptions that must be met before using the RD design. The first requirement is strict observance to the cut-off point. Overriding the assignment criterion has the potential for inducing selection bias.

Second, it is important to correctly identify the functional relationship between assignment measure and the outcome variable. If the association is linear, or can be transformed to achieve linearity (by transforming either one or both variables), the analysis is more readily interpreted. However, a misspecification of the model may lead to inaccurate conclusions being drawn about the treatment effect.

Third, the pre-test sample size must be large enough to support use of regression analysis to estimate the pre- and post-test relationship. Small sample sizes will result in lower power and thus a higher susceptibility to making a type II error (i.e. not recognizing a treatment effect when in fact there is one) (Linden *et al*. 2004b).

Fourth, all individuals in the study, whether ultimately assigned to treatment or control, must be drawn from the same population. In addition, all individuals should have an equal probability of being included in the treatment group, had the cut-off point been relocated to another point along the continuum (Shadish *et al*. 2002).

Finally, it is assumed that all participants in the treatment receive the same level and amount of intervention. As DM programmes typically assign high-risk participants to a nursing intervention and less-risk participants to a mailing and/or internet-based interventions, the RD model must be modified to handle multiple cut-off points in order to satisfy this assumption (details of this procedure are provided in Appendix 1).

Summary and conclusions

This paper has introduced the RD design as being possibly the closest method to the RCT for evaluating DM programme effectiveness. The use of a rigorously adhered to cut-off point for assigning individuals to the programme or to the control, is what achieves an unbiased estimate of a treatment effect. This is roughly equivalent to the random assignment in an RCT, or the use of an instrumental variable (Angrist *et al*. 1996), commonly found in the economics literature. Using the RD design eliminates the typical concerns plaguing DM evaluation, that is, the impact of selection bias and regression to the mean.

In order to implement this design correctly in DM, several basic changes to the current strategies must be made. First, a more appropriate identification and stratification process must be employed than that which is currently in use. This can be done by using clinically based criteria, survey-based psychosocial indices, or claims-based predictive models. The important feature of any of these methods is that the scoring mechanism is on either a continuous or an ordinal scale, and that all individuals with the given disease are scored.

Second, strict adherence to the cut-off point is essential. Any deviation from this rule will potentially bias the estimate of treatment effect, and limit the validity of the study findings. This becomes even more important in cases where multiple cut-off points are used to distinguish between levels of intervention.

Finally, as is the case with any observational study design, the choice of outcome measure should be made based on reasonable expectations for a causal effect of the intervention. Expecting cost reductions based on an intervention that targets behavioural modification regarding adherence to treatment may not be realistic, at least in the short run. Similarly, outcome measures such as cost that are susceptible to measurement error and other biases should be avoided. More appropriate measures are those that

remain relatively unaffected by confounding over time and can be causally linked back to the intervention (Linden *et al*. 2003a,b). Such measures may include changes in disease severity, functional status, improvement of self-management techniques, adherence to guidelines, or health related quality of life.

Acknowledgements

We wish to thank William Trochim and Joseph Cappelleri for their generous contribution in reviewing this manuscript and providing excellent and helpful comments.

References

Angrist J.D., Imbens G.W. & Rubin D.B. (1996) Identification of causal effects using instrumental variables. *Journal of the American Statistical Association* **91**, 444–455.

Cappelleri J.C., Trochim W.M.K., Stanley T.D. & Reichardt C.S. (1991) Random measurement error does not bias the treatment effect estimate in the regression-discontinuity design: I. The case of no interaction. *Evaluation Review* **15** (4), 395–419.

Cousins M.S., Shickle L.M. & Bander J.A. (2002) An introduction to predictive modeling for disease management risk stratification. *Disease Management* **5** (3), 157–167.

Disease Management Association of America (2004) *Definition of Disease Management.* Available at: http://www.dmaa.org/definition.html (retrieved June 23).

Finkelstein M.O., Levin B. & Robbins H. (1996a) Clinical and prophylactic trials with assured new treatment for those at greater risk: a design proposal. *American Journal of Public Health* **86** (5), 691–695.

Finkelstein M.O., Levin B. & Robbins H. (1996b) Clinical and prophylactic trials with assured new treatment for those at greater risk: II. Examples. *American Journal of Public Health* **86** (5), 696–705.

Høglend P. (1996) Long-term effects of transference interpretations: comparing results from a quasi-experimental and a naturalistic long-term follow-up study of brief dynamic psychotherapy. *Acta Psychiatrica Scandinavica* **93**, 205–211.

Linden A., Adams J. & Roberts N. (2003a) An assessment of the total population approach for evaluating disease management program effectiveness. *Disease Management* **6** (2), 93–102.

Linden A., Adams J. & Roberts N. (2003b) *Evaluation methods in disease management: determining program effectiveness.* Position paper commissioned by the Disease Management Association of America (DMAA). Available at: http://www.dmaa.org/PDFs/Evaluation_Methods_in_DM.pdf

Linden A., Adams J. & Roberts N. (2004a) The generalizability of disease management program results: getting from here to there. *Managed Care Interface* **7**, 38–45.

Linden A., Adams J. & Roberts N. (2004b) Using an empirical method for establishing clinical outcome targets in disease management programs. *Disease Management* **7** (2), 93–101.

Linden A. & Roberts N. (2004) Disease management interventions: what's in the black box? *Disease Management* **7**, 275–291.

Luft H.S. (1990) The applicability of the regression-discontinuity design in health services research. In: *Research Methodology: Strengthening Causal Interpretations of Nonexperimental Data. AHCPR Conference Proceedings, PHS 90-3545* (eds L.B. Sechrest, E. Perrin & J. Bunker), pp. 141–143. Agency for Health Care Policy and Research, Rockville, MD.

McDowel I. & Newell C. (1996) *Measuring Health: A Guide to Rating Scales and Questionnaires*, 2nd edn. Oxford University Press, New York, NY.

Reichardt C.S., Trochim W.M.K. & Cappelleri J.C. (1995) Reports of the death of regression-discontinuity analysis are greatly exaggerated. *Evaluation Review* **19** (1), 39–63.

Rubin D.B. (1977) Assignment to treatment group on the basis of a covariate. *Journal of Educational Statistics* **2**, 1–26.

Shadish S.R., Cook T.D. & Campbell D.T. (2002) *Experimental and Quasi-Experimental Designs for Generalized Causal Inference.* Houghton Mifflin, Boston, MA.

Thistlethwaite D. & Campbell D. (1960) Regression-discontinuity analysis: an alternative to the ex post facto experiment. *British Journal of Educational Psychology* **51**, 309–317.

Trochim W. (1984) *Research Design for Program Evaluation: The Regression-Discontinuity Approach*. Sage Publications, Beverly Hill.

Trochim W.M.K. (1990) The regression discontinuity design. In: *Research Methodology: Strengthening Causal Interpretations of Nonexperimental Data. AHCPR Conference Proceedings, PHS 90-3545* (eds L.B. Sechrest, E. Perrin & J. Bunker), pp. 119–139. Agency for Health Care Policy and Research, Rockville, MD.

Trochim W.M.K., Cappelleri J.C. & Reichardt C.S. (1991) Random measurement error does not bias the treatment effect estimate in the regression-discontinuity design. II. When an interaction effect is present. *Evaluation Review* **15**, 571–604.

Appendix 1. Regression discontinuity model specification

Basic model

The basic RD model (Trochim 1984, 1990; Shadish *et al*. 2002) is as follows:

$$Y = \beta_0 + \beta_1 Z_i + \beta_2 (X_i - X_c) + e_i \quad (1)$$

Where Y is the dependent or outcome variable, β_0 is the intercept at the cut-off point, Z_i is the dichotomous assignment variable (1 = treatment, 0 = control), β_1 is the estimated treatment effect, β_2 is the linear slope parameter, $(X_i - X_c)$ is a given individual's pre-test score minus the cut-off value, and e_i is the random error term. The reason that an individual's pre-test score is transformed, via $X_i - X_c$, is to set the intercept β_0 equal to the cut-off so that estimates of treatment effects are made at the cut-off value instead of at 0 (Trochim 1990). The main treatment effect is easily identified by a statistically significant P-value in the β_1 coefficient.

Expanded model to handle interactions and non-linearity

Equation 1 specifies only the existence of a main treatment effect. However, there may be an interaction effect between the assignment variable Z_i and the transformed pre-test variable X_i. In such a situation, a participant in the treatment group located near the cut-off would benefit less than another participant with a score higher on the scale. The existence of an interaction effect can be determined by adding a term to the equation $Z_i(X_i - X_c)$ and reviewing the P-value of that coefficient.

Additionally there may be a concern that the data are non-linear and thus estimating a linear model may bias the results. Non-linearity can occur if the variables are not normally distributed, there are chance outliers, or there exists a floor/ceiling effect (Trochim 1984; Trochim *et al*. 1991; Shadish *et al*. 2002). When non-linearity is suspected, higher order terms should be added to the equation. Trochim (1984, 1990) suggests over-fitting the model by two orders higher than what the model indicates upon visual inspection. Therefore, if the data appear to be linear, squaring the term should suffice. While this may result in over-fitting the model, any non-significant terms can be removed from the analysis later resulting in a correctly specified and efficient model. A model with the additional terms (Trochim 1984, 1990; Shadish *et al*. 2002) is as follows:

$$Y = \beta_0 + \beta_1 Z_i + \beta_2 (X_i - X_c) + \beta_3 Z_i (X_i - X_c) + \beta_4 (X_i - X_c)^2 + \beta_5 Z_i (X_i - X_c)^2 + e_i \quad (2)$$

where the terms are as defined in Equation 1, with the addition of interaction terms $Z_i(X_i - X_c)$ and higher order terms $(X_i - X_c)^2$ and $Z_i(X_i - X_c)^2$.

Analysing multiple cut-off points

In DM programmes where there is more than one intervention, Equation 1 or 2 can be estimated multiple times, each time changing the cohort criteria for the dichotomous assignment variable Z_i:

Model 1: 1 = Low level intervention (e.g. mailings), 0 = control

Model 2: 1 = High level intervention (nurse case manager), 0 = control

Model 3: 1 = High level intervention, 0 = Low level intervention

Accordingly, it can then be determined whether a treatment effect is evident between (1) each intervention level compared to the control group and (2) each level of intervention compared to each other.