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RESEARCH METHODS

Geographic Information Systems to Assess External Validity in Randomized Trials

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Introduction: To support claims that RCTs can reduce health disparities (i.e., are translational), it is imperative that methodologies exist to evaluate the tenability of external validity in RCTs when probabilistic sampling of participants is not employed. Typically, attempts at establishing post hoc external validity are limited to a few comparisons across convenience variables, which must be available in both sample and population. A Type 2 diabetes RCT was used as an example of a method that uses a geographic information system to assess external validity in the absence of a priori probabilistic community-wide diabetes risk sampling strategy.

Methods: A geographic information system, 2009–2013 county death certificate records, and 2013–2014 electronic medical records were used to identify community-wide diabetes prevalence. Color-coded diabetes density maps provided visual representation of these densities. Chi-square goodness of fit statistic/analysis tested the degree to which distribution of RCT participants varied across density classes compared to what would be expected, given simple random sampling of the county population. Analyses were conducted in 2016.

Results: Diabetes prevalence areas as represented by death certificate and electronic medical records were distributed similarly. The simple random sample model was not a good fit for death certificate record (chi-square, 17.63; p=0.0001) and electronic medical record data (chi-square, 28.92; $p<0.0001$). Generally, RCT participants were oversampled in high−diabetes density areas.

Conclusions: Location is a highly reliable "principal variable" associated with health disparities. It serves as a directly measurable proxy for high-risk underserved communities, thus offering an effective and practical approach for examining external validity of RCTs.

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INTRODUCTION

Community-level interventions that were evaluated as RCTs have potential to reduce health disparities if positive results are translated into cost effective and efficacious programs for high-risk underserved communities.[1–3] RCTs provide a valid assessment of the trial's effects specific to the study sample (i.e., internal validity), but unless the sample represents the target population (i.e., external validity), their translational potential may be limited.[4–7]

Most RCTs are limited in size and cannot enroll participants using population-based random recruitment methods to yield large representative samples. More likely, individuals are recruited using a purposive sampling approach that sets recruitment goals based on race,

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ethnicity, or gender to ensure heterogeneity.[4] Frequently, participation and attrition rates are used to assess how subgroups responded to the intervention or weighting strategies and post-stratification analysis are employed to evaluate outcomes among subgroups.[5] However, few methods assess how well a trial included those most vulnerable to the condition of interest.[4] Using measures such as age, race, ethnicity, and gender, samples are sometimes compared to those who were screened but not enrolled,[8] patients in healthcare networks with a similar diagnosis,[9] or population-based samples from chronic disease prevalence assessments.[10] Regardless of method, attempts at establishing representativeness after the fact are infrequent.[11–13] Even when efforts are made to establish external validity, appropriate variables for such analyses are often not available. When target populations live in places experiencing high chronic disease rates, standard demographic variables may not reflect resources unevenly distributed across communities, such as healthy food sources, physical activity opportunities, healthcare access, housing conditions, and transportation.[1,14,15] These characteristics are important to consider when comparing a trial sample to the target population; however, characterizing individuals and communities across diverse measures is a challenge.[16]

Where an individual lives is probably the most comprehensive single measure of SES and community conditions.[17] Geographic location can be directly measured and observed and is a natural composite of income, safety, education, housing, access to health care, and other factors. The "principal variable" characteristics[18] of geographic location serve as a proxy for a wide range of measures known to be highly correlated to where a person lives.[19,20] Type 2 diabetes mellitus is a chronic disease that is not uniformly distributed across geographic areas.[21] Higher prevalence of Type 2 diabetes is generally found in underserved populations, that is, those living in communities with few health-promoting resources and less access to care.[20,22–24]

Over the past 25 years, there has been tremendous growth in the use of geographic information systems (GIS) as tools to understand the influence of location on health.[19,24–26] GIS can map residential addresses of those affected by particular health conditions and generate spatial patterns that define areas where the prevalence of health conditions vary.[26] These areas can be characterized using geo-referenced databases to identify environmental, social, economic, and healthcare resources shared by residents.[26–29] The spatial patterns of Type 2 diabetes have been linked to community resources for care or prevention, [17,30,31] and have helped to inform the design of interventions to reduce diabetes-related health disparities.[26,32,33]

This report describes a proposed method for assessing external validity in a Type 2 diabetes RCT in which participants were randomized to treatments but not randomly sampled to represent the geographic distribution of community-wide Type 2 diabetes risk. Under assumptions of simple random sampling and location as a "principal variable," the method uses GIS to examine the geographic variation in participants relative to the variation in estimated population prevalence of Type 2 diabetes.

METHODS

Study Sample

The RCT, Lifestyle Intervention for Treatment of Diabetes (LIFT),[34] was a two-arm randomized, community-based clinical trial designed to compare the effects of two 12-month intervention strategies (lifestyle education delivered by community health workers or group-based diabetes self-management education) on the cardiovascular disease risk of overweight and obese adults with Type 2 diabetes.[34] Recruitment of minority and low-income individuals was a key objective of LIFT.[34] However, there was no probabilistic sampling to ensure that participants were recruited from areas with the highest risk of Type 2 diabetes.

Recruitment used the medical center's electronic medical record (EMR) system (Epic, Verona, WI) and non-EMR sources (referrals, community outreach, and local media).[34] Recruitment began in March 2013 and was completed in February 2015. The total number of LIFT participants was 260. Only the 220 participants residing in Forsyth County were included in the analysis.

Approach

The LIFT trial was used as an example to show how GIS can be used to assess the representativeness of an RCT. This proposed method is not concerned with the intervention's effects, but rather the RCT serves as an example of a technique for evaluating external validity when participants are randomly assigned but not randomly selected. This was accomplished in three steps. First, the spatial distribution of diabetes prevalence was assessed by using administrative databases to identify residential locations of individuals who represent the target population. Second, diabetes prevalence, based on the incidence of cases, was displayed on shaded maps with colors representing density levels, which categorized areas based on the prevalence of diabetes. Third, an expected frequency model (chi-square goodness of fit statistic/analysis) was used to evaluate the degree to which spatial distribution of LIFT participants varied across diabetes density areas when compared to what would be expected, given simple random sampling of the population.

GIS Mapping of Diabetes Prevalence

Two databases were used to assess the geographic distribution of county-wide diabetes risk. The first contained Forsyth County death certificate records (DCRs) of those for whom diabetes was listed as the primary or contributing cause of death for the years 2009–2013 (identified by ICD-10 codes E10–E14). This database was provided by Forsyth County Department of Public Health, following approval from North Carolina Department of Health and Human Services. The second source of diabetes prevalence was obtained from the EMR system of the Wake Forest School of

Medicine for the years 2013–2014.[35] This was the same database that was used to help identify potential LIFT participants. Records were obtained following approval of the Wake Forest School of Medicine IRB for a waiver of consent and Health Insurance Portability and Accountability Act authorization to obtain medical record number, age, race, gender, and postal address for patients living in Forsyth County and identified by the EMR system as having diabetes.

Addresses from DCR and EMR databases were geocoded to point locations[35] using a Composite Locater in Esri's ArcMap, version 10.3.1. The DCR database contained 1,512 records, of which 413 had diabetes listed as the primary cause of death. After post office boxes, homeless listings, and non-county ZIP codes were removed, 1,476 remained; 98%, or 1,447, had addresses that were successfully geocoded. The EMR database contained 5,120 diabetes patients that yielded 4,768 patients that were successfully geocoded (93%). These rates are consistent with typical geocoding rates >90%.[26] Point locations for each database were separately mapped to identify the geographic distribution of diabetes cases with Esri's Spatial Analyst extension using the Kernel Density tool. This resulted in seven density classes (Classes 1–7, low to high density) based on equal intervals.[36] The smoothing coefficient associated with the kernel density was chosen to produce a density map with sufficient resolution, while maintaining a continuous topography over the density classes.

Color-coded density maps (seven colors) of Forsyth County were generated for both databases, that is, hotter colors equate to higher density. The locations (addresses) of the 220 LIFT participants were superimposed on both maps. Each participant was assigned to a DCR and EMR density class based on the point location associated with their residential address.

Statistical Analysis

The purpose of the analysis was to determine whether LIFT participants could be considered a quasi-random sample of Forsyth County residents with diabetes. The method used an expected frequency model of LIFT participants across the density classes based on the percentage of county residents living in the geographic areas defined by each class. In separate chi-square goodness of fit statistic/analyses for each database, the distribution of the expected number of LIFT participants given simple random sampling of county residents was compared to the observed number of LIFT participants by diabetes density class. These analyses were completed in 2016. Statistical analysis used JMP Pro, version 12.0.1.

RESULTS

Figures 1 and 2 present geocoded density maps of Forsyth County as derived from DCR and EMR

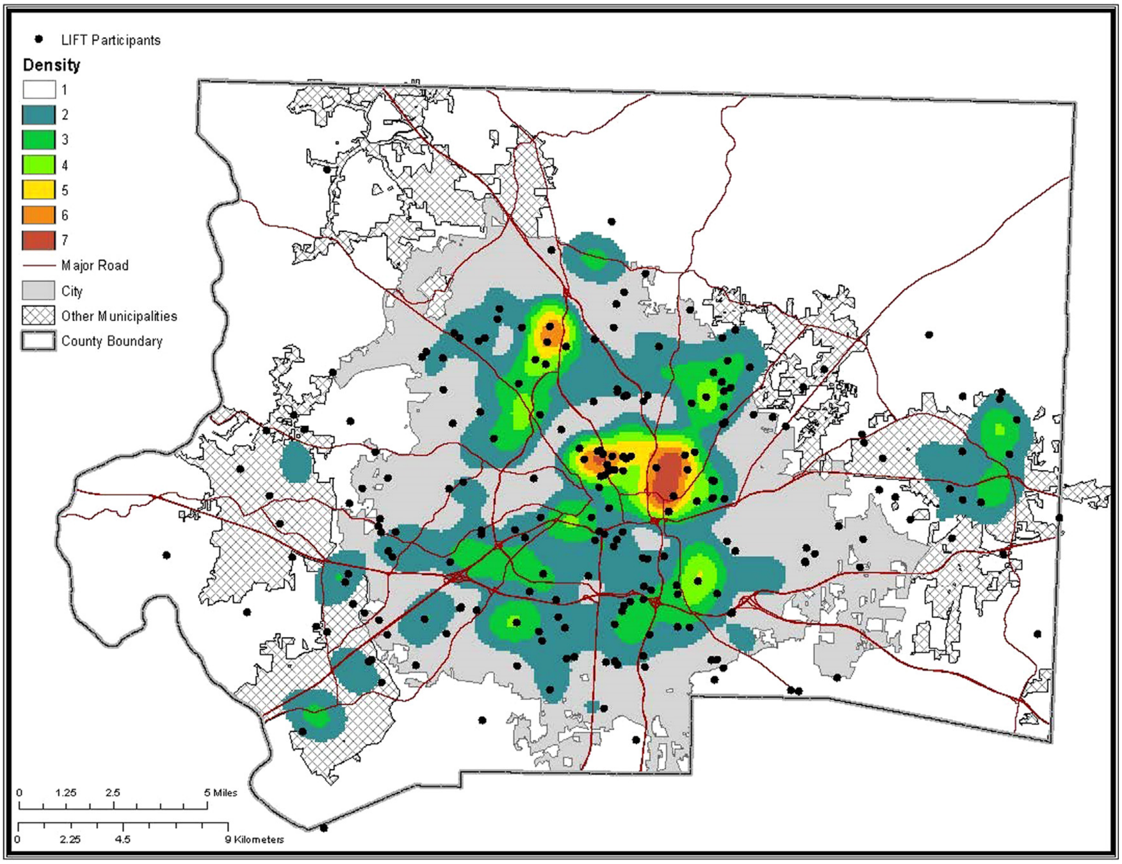

Figure 1. Map of death certificate records.
The geographical distribution of 1,447 deaths of Forsyth County residents for whom diabetes was listed as the immediate or contributing cause of death in the years 2009 to 2013. Higher numbers for color-coded densities represent higher density of diabetes-related deaths. The individual points on the map represent the residential addresses of 220 Lifestyle Intervention for Treatment of Diabetes (LIFT) participants.

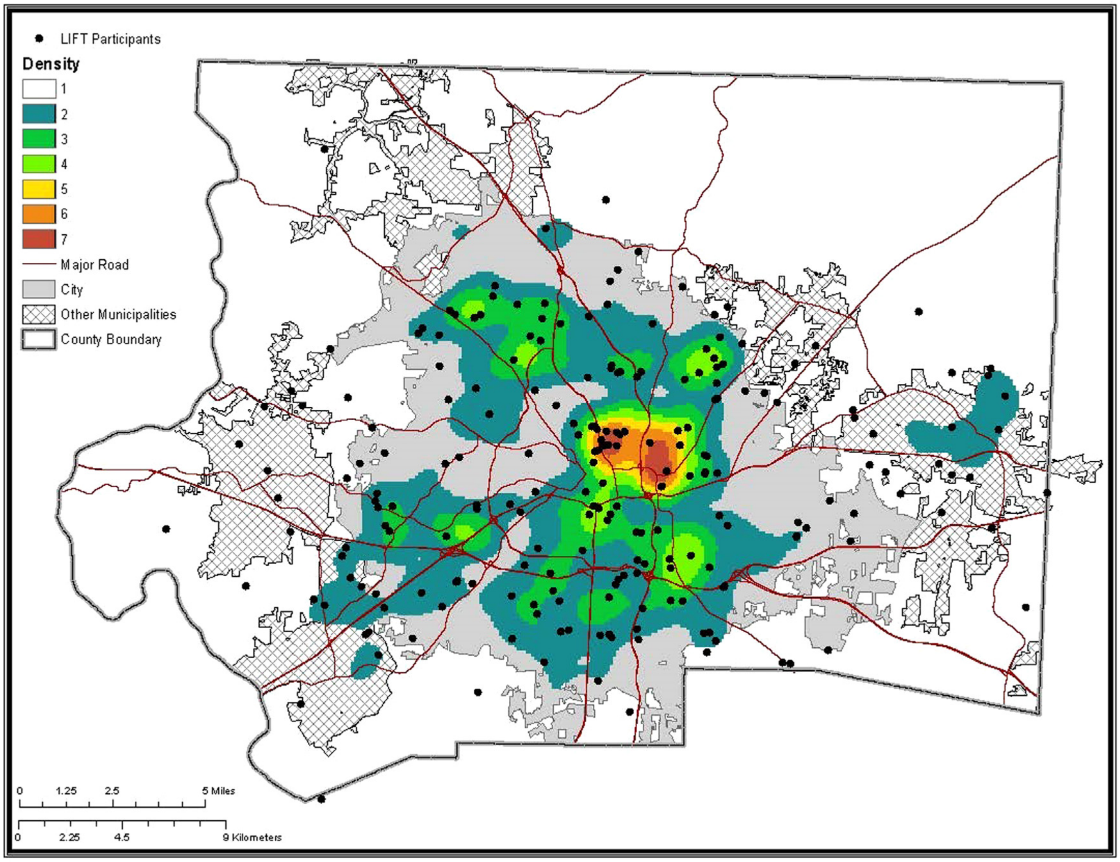

Figure 2. Map of electronic medical records.
The geographical distribution of 4,768 patients with diabetes identified from the electronic medical record system of Wake Forest Baptist Hospital Medical Center. Higher numbers for color-coded densities represent higher density of diabetes patients. The individual points on the map represent the residential addresses of 220 Lifestyle Intervention for Treatment of Diabetes (LIFT) participants.

databases, respectively, and also display residential locations of 220 LIFT participants. Maps show similar high-density (red, amber, and yellow) areas of either diabetes-related deaths (DCR) or diabetes patients (EMR) around the center of the city of Winston-Salem (gray shading) and moderate densities (blue, teal, and green) throughout the city. The difference between the maps is minor; the high-density area on the DCR map in northwest Winston-Salem is not seen in the EMR map. As might be expected owing to lower population density in areas outside the city, distribution of LIFT participants was less dense outside the metropolitan area. Although participants appeared to be distributed randomly across the county, there was an indication that they were clustered in and around high-density areas. However, this could have been a consequence of population density and not reflect the density of diabetes deaths or patients.

The method evaluated whether the distribution of LIFT participants departed from what would be expected if participants were chosen through simple random sampling or if clustering observed in Figures 1 and 2 was influenced by diabetes prevalence. To do this, population values for each density class were used to model how many LIFT participants would be expected in each of the seven densities. Esri Community Analyst provided the number of Forsyth County residents living in areas defined by each density class. To avoid statistical problems associated with sparse frequency tables, the seven classes were collapsed into three diabetes density categories: 1 (low [white]), 2–4 (moderate [blue, teal, and green]), and 5–7 (high [yellow, orange, and red]). Tables 1 (DCR data) and 2 (EMR data) summarize results of the chi-square analysis for goodness of fit of LIFT participants to a model that assumes simple random sampling. In Table 1, the total chi-square value for DCR data was 17.49, which suggested that the simple random sample model was not a good fit (p=0.0001). Examination of residuals and individual cell chi-square values (Table 1) indicated that participants were over-sampled from high-density areas; approximately 80% of the total chi-square value was a result of the over-sampling in the high diabetes density areas. For EMR

Table 1. Observed Versus Expected Distribution of LIFT Participants Based on County Population by Diabetes Death Certificate Density

χ^2 Components	Total	Low density (Class[a] 1)	Moderate density (Classes 2–4)	High density (Classes 5–7)
Forsyth county population	350,670	181,091 (51.6)	153,438 (43.8)	16.141 (4.6)
Observed LIFT participants, *n*	220	95 (43.2)	103 (46.8)	22 (10.0)
Expected[b] LIFT participants, *n*	220	113.5 (51.6)	96.4 (43.8)	10.1 (4.6)
Residual[c]	0	−18.5	6.6	11.9
χ^{2d} (goodness of fit)	17.49	3.02 (17.3)	0.45 (2.5)	14.02 (80.2)

Note: Values in parentheses are percentages of total.
[a]Density categories determined from GIS mapping (Figure 1).
[b]Expected=Forsyth County density category percentage (0.01)×total number of LIFT participants (n=220).
[c]Residual=observed−expected.
[d]χ^2=residual^2/expected (p=0.0001, df=2).
LIFT, Lifestyle Intervention for Treatment of Diabetes.

data (Table 2), the goodness-of-fit chi square (28.77, $p<0.0001$) indicated a statistically significant departure from the simple random sampling model. Residuals and cell chi-square values indicated oversampling in high and undersampling in low areas. DCR and EMR results differed in one respect. For EMR data, the percentage of total chi-square values from the high and low diabetes density areas was approximately 49% and 35%, respectively. This is in contrast to DCR data in which the majority of the total chi-square value was attributable to oversampling in high-density areas.

DISCUSSION

This study demonstrates the use of GIS technology to assess the external validity of RCTs. As an example, the geographic distribution of participants in a RCT of a Type 2 diabetes lifestyle intervention was evaluated as to whether this distribution deviated from what would be expected, given simple random sampling of the population and how diabetes prevalence was consistent with geographic distribution of the RCT sample. The RCT used minority status as a criterion standard for Type 2 diabetes risk (48% of the LIFT participants were African American), but it was important to determine if this actually reflected the geographic distribution of diabetes risk. The strategy was to identify community-wide diabetes prevalence using residential locations of individuals who died from diabetes-related causes and patients with diagnosed diabetes. Participants' residential locations, when superimposed on GIS maps, appeared to be generally randomly distributed. By looking across areas of low, moderate, and high diabetes density and comparing the expected number of participants based on population density to the actual number who lived in these areas, a bias toward oversampling in moderate- and high-density areas was identified. This does not mean that the RCT was not representative, but rather, as intended, that LIFT participants reflected community-wide diabetes risk.

Table 2. Comparison of Observed and Expected Distribution of LIFT Participants Based on County Population by Diabetes Patient Density Category

χ^2 Components	Total	Low density (Class[a] 1)	Moderate density (Classes 2–4)	High density (Classes 5–7)
Forsyth county population	350,670	176,209 (50.2)	160,625 (45.8)	13,836 (4.0)
Observed LIFT participants, *n*	220	77 (35.0)	123 (55.9)	20 (9.1)
Expected[b] LIFT participants, *n*	220	110.4 (50.2)	100.8 (45.8)	8.8 (4.0)
Residual[c]	0	−33.4	22.2	11.2
χ^{2d} (goodness of fit)	28.77	10.10 (35.1)	4.42 (15.4)	14.25 (49.5)

Note: Values in parentheses are percentages of total.
[a]Density categories determined from GIS mapping (Figure 2).
[b]Expected=Forsyth County density category percentage (0.01)×total number of LIFT participants (n=220).
[c]Residual=observed−expected.
[d]χ^2=residual^2/expected ($p<0.0001$, df=2).
LIFT, Lifestyle Intervention for Treatment of Diabetes.

The applicability of community-based RCTs depends how well participants reflect their communities and those most vulnerable to these conditions.[13] Kruskal and Mosteller[37–39] formulate the argument that external validity (representativeness) is, in practical application, a relative term. They make the case that representativeness may be "good enough" given the purpose and intent of the RCT and, unless the sample is randomly selected from the target population, the sample itself represents a random variable, that is, it reflects some aspects of the target population and not others. Their general recommendation is to evaluate external validity with an open mindset rather than fixed notion that the sample is or is not representative of the target population. The use of graphical analysis coupled with subjective probability (supported by simple statistical modeling) is consistent with these concepts.[40,41]

Internal validity of RCTs is assessed routinely by comparing groups using characteristics such as race, gender, education, income, comorbidities, and lifestyle characteristics (e.g., BMI, smoking status, or alcohol usage).[13] However, few trials report how enrollment was distributed across communities and within areas that have the greatest need.[12,13,42] Current methods of evaluating external validity rely on some form of testing differences between sample estimates and population parameters. These procedures are limited, as they require measurement of variables common to the sample and target population of interest.[4,17] As external validity is a design and not a statistical concept, it is not possible to obtain a quantitative estimate reflecting the superiority of one external validity methodology over another. However, it is possible to recognize qualitative traits specific to the proposed approach that are not found in other techniques. Unlike techniques that simply compare sample estimates to population parameters, this approach provides a visual comparison of the spatial distribution of the obtained sample and the specific population at risk. Furthermore, the method only requires knowledge of study participants' addresses and those of the target population. This approach capitalizes on geographic location as a principal variable,[18] which reflects variation in a wide range of place-based characteristics associated with health.[19,20] This information may include, but is not limited to, age[30]; education[43]; income[29,43]; racial segregation[14,44]; employment[45]; household composition[14,43]; healthcare access[14,31]; comorbidities[46,47]; availability of recreational facilities[19,29]; and quality of food sources.[15,19] Geographic location reflects multivariate effects of unequal distribution of resource and its influences on physical and social environments.[14,15,44,48] Although not concerned with characteristics of location as a principle variable, Richardson et al.[49] have also advocated for GIS for post hoc assessment of spatial orientation across geographic area as a means to evaluate external validity.

Limitations

The effectiveness of the method assumes adequate reliability and validity of two administrative databases that provided diabetes prevalence information. Ninety-eight percent of diabetes-related deaths and 93% of EMR patients were geocoded; these rates were consistent with typical rates $>90\%$[26] and reports of geocoding similar databases.[28,50] The 2005 North Carolina death certificate registry was successfully geocoded in 93% of cases of all deaths and 92% of deaths from diabetes-related causes[50] and 88% of 9,700 patients with Type 2 diabetes from the University of California Davis Health System EMR system were successfully geocoded.[28] There will always be addresses that cannot be geocoded. Edwards and colleagues[50] found geocoding rates were lower in rural areas and among racial and ethnic groups. Misclassification error of assigning diabetes as cause of death may have affected the density mapping. DCRs are improving but continue to underestimate diabetes-related deaths.[51] Diabetes deaths and patients were surrogates for diabetes prevalence. Areas with higher death rates could have a higher diabetes prevalence or more severe diabetes than other areas. Also, it was not possible to obtain EMR records for patient visits outside of the medical center. However, from two independent sources of diabetes prevalence (DCRs and EMRs), very similar patterns were identified.

CONCLUSIONS

The use of GIS offers a practical and straightforward alternative to common techniques that quantify representativeness by using limited measures available for both the sample and population. True representativeness can only be assumed if recruitment and enrollment procedures were defined using some form of probabilistic sampling. It should be understood that without random sampling, there is no correct answer to the question of external validity. Therefore, establishing representativeness after the fact in non-randomized samples must involve some degree of subjective probability using a more graphical and Bayesian heuristic and not traditional hypothesis testing with its Neyman–Pearson accept/reject concepts.[40,41] Through graphical analysis, assumption of location as a highly reliable principal variable, and simple statistical modeling, this method offers an effective approach to improve assessments of the external validity of community-based RCTs.

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