ELSEVIER

Contents lists available at ScienceDirect

Contemporary Clinical Trials



journal homepage: www.elsevier.com/locate/conclintrial

Rationale, design, and baseline data of a cross-national randomized trial on the effect of built shade in public parks for sun protection



David B. Buller^{a,*}, Suzanne Dobbinson^b, Dallas R. English^{c,d}, Melanie Wakefield^b, Mary Klein Buller^a

^a Klein Buendel, Inc., Golden, CO, USA

^b Centre for Behavioural Research in Cancer, Cancer Council Victoria, Melbourne, VIC, Australia

^c Epidemiology and Biostatistics, Melbourne School of Population and Global Health, University of Melbourne, Melbourne, VIC, Australia

^d Cancer Epidemiology Centre, Cancer Council Victoria, Melbourne, VIC, Australia

ARTICLE INFO

Article history: Received 17 October 2016 Received in revised form 30 January 2017 Accepted 4 February 2017 Available online 07 February 2017

Keywords: Shade Sun protection Public parks Randomized trial

ABSTRACT

Environments can be structured to reduce solar ultraviolet radiation (UV) exposure to prevent skin cancer. A prospective randomized trial is being conducted to test whether introducing shade sails in passive recreation areas (PRAs) in public parks will increase use and decrease UV exposure in the shaded compared to unshaded PRAs. Shade effects will be compared between Melbourne, Australia and Denver, USA. The trial enrolled 145 public parks with PRAs suitable for shade construction and randomized parks to intervention or control in a 1:3 ratio. Use of PRAs and UV levels were recorded at each park by trained observers during 30-minute periods on four weekend days in each of two summers (pretest and posttest). Shade sails were constructed between the summers. Given low numbers of users at pretest, the outcome measure was modified to use of the PRA (use vs. no use) and unit of analysis to the individual observation. Observations (n = 580) occurred on average 29 days from the summer solstice and 55 min from solar noon in warm weather (mean = 26.2 °C) with some cloud cover but only slight or no wind. Typically, PRAs had benches and picnic tables and were located near playgrounds. PRAs were in use during 13.3% of observations (mean = 0.41 users). UV over 30-minutes at the PRA boundary (mean = 3.2 standard erythemal dose [SED]) and center (mean = 3.3 SED) was high. Shade for skin cancer prevention has been understudied. This study will address this gap by determining whether purpose-built shade structures promote greater use of shaded areas within public parks.

© 2017 Published by Elsevier Inc.

1. Introduction

Skin cancer is a significant burden in countries with high ultraviolet radiation (UV) levels and large light-skinned populations [1–9]. Prevention involves reducing UV exposure by structuring environments to support sun safety (e.g., providing shade and altering outdoor schedules) and promoting personal protection (i.e., limiting time in the sun and wearing protective clothing [10,11] and broad-spectrum sunscreens [12–18]).

Shade can reduce UV exposure. Unlike other practices, shade requires little personal planning, provides a visual reminder for sun safety, and may attract individuals at high-risk or with unfavorable attitudes towards sun protection. For example, in Melbourne secondary schools, adolescents who typically were aware of skin cancer but resistant to personal protection used rather than avoided newly shaded areas [19]. Permanent purpose-built shade is optimal to provide shade at desired locations, especially when warm light-colored shade of a relatively

E-mail address: dbuller@kleinbuendel.com (D.B. Buller).

large size [20] is constructed that provides shade during the hours close to solar noon in seasons when UV is at its peak [21] Some shade cloth can reduce UV levels considerably (blocking at least 94% of UV [22]) at an affordable cost [23].

Our team has undertaken a randomized trial to examine prospectively the impact of built shade on use of passive recreation areas (PRAs) and potential UV exposure in public parks. Public parks are an important setting for outdoor recreation. Shade is a desirable feature in parks [24–28] and thus should be used by park visitors. The following primary hypothesis was tested:

H1: Introduction of shade sails over PRAs will increase the number of individuals using those PRAs.

Social ecological models (SEMs) help conceptualize the potential effect of built environments on health behavior in the context of multilevel societal and environmental influences [29–31]. Built environments are those created or significantly modified by people [32]. SEMs have been employed to explain how density of tanning bed facilities is associated with youth tanning [33] and to create interventions in pools [34] elementary schools [35] and communities [36,37]. In SEMs, the physical environment, of which shade is a part, can have both direct and indirect effects on behaviors [38–45] (see Fig. 1). Direct effects may include

^{*} Corresponding author at: Klein Buendel, Inc., 1667 Cole Boulevard, Suite 225, Golden, CO 80401, USA.

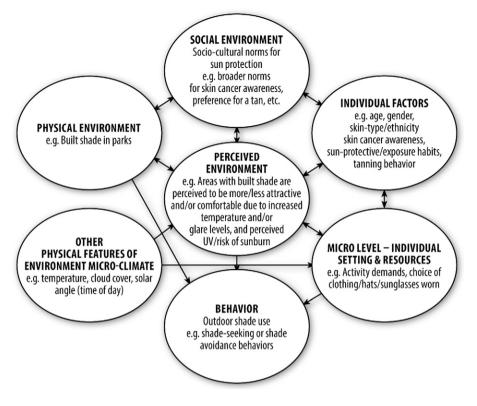


Fig. 1. Social ecological model applied to influence of built shade.

increasing the number of individuals shaded, providing a visible cue for protection, and enabling ready access to protection. Indirect effects may occur by changing societal norms [46–48] regarding sun protection [29, 45]. Australia and the United States have different histories of sun safety promotion that may have produced different social (i.e., sun protection norms) and physical environments (i.e., built shade) such that built shade might be used more readily in Australia than the United States. The trial also compared the use of built shade in public parks in the United States and Australia by testing the following primary hypothesis:

H2: City will moderate use of the shade sail such that increase in number of people using PRAs covered by the shade sails in the parks in Melbourne will be larger than the increase in number of people in Denver.

The value of built shade for sun protection is to reduce UV in the shaded locations. To confirm this prediction, the following secondary hypothesis was evaluated:

H3: Introduction of shade sails over PRAs will reduce the average UV exposure in the PRA compared to PRAs not shaded.

2. Materials and methods

2.1. Experimental design

The trial was performed in Denver, Colorado, USA and Melbourne, Victoria, Australia. A stratified, randomized pretest-posttest controlled design was employed. The protocol included 160 PRAs (80 in each city), of which 40 (20 in each city) were to be selected at random to have shade sails constructed. Parks were selected and enrolled in three annual waves to make it more feasible to manage the trial and stay within annual budgetary limits. The sample size was selected based on a priori statistical power calculations to detect an increase of 3.8 individuals on average using the shaded PRAs during each observation compared to no change in the use of control unshaded PRAs. The unequal 1:3 allocation ratio to treatment (shaded) versus control (unshaded) was adopted because of the cost of building the shade

structures, limiting the number that could be built. The protocol for randomization to shade sail construction or control was stratified by wave and within each wave by the four municipalities in Melbourne and the four park maintenance areas in Denver to ensure that shade sails were distributed throughout the participating municipalities. PRAs were audited, selected, enrolled and randomized in three annual waves in each city to manage project resources. All procedures were approved by the Western Institutional Review Board and the Cancer Council Victoria Institutional Research Review Board.

2.2. Changes to design after commencement of the trial

After the trial began the number of PRAs was reduced to 144 (72 in each city), with 36 (18 in each city) to be shaded, because of budget constraints. These constraints were created by unfavorable changes in foreign exchange rates between Australian and US dollars that reduced the amount of funds available to pay for shade sails in Australia. Pilot testing prior to the trial suggested that on average 4.2 individuals would be observed using PRAs during each observation period at baseline and the expected pre-post change of 3.8 was based on our secondary school study [19,49]). However, fewer PRAs were in use during the baseline observations than expected so stratification by baseline use was not feasible but was by city and wave. In addition, it was necessary to include four municipalities in Melbourne to include sufficient parks. Given these municipalities had distinct levels of natural shade and age of housing it was decided to stratify by municipality in Melbourne, and for comparability by park maintenance areas in Denver, to distribute shade sales across them. As discussed below, these changes required the primary outcome for the two primary hypotheses to be changed from total number of users of PRAs to any use. New power calculations were performed for the two primary hypotheses to determine whether the modified trial, with reduction to 144 PRAs and altered primary outcome, was feasible (see below). The small number of PRAs in use at baseline also made it impossible to obtain individual-level data on social norms and sun protection and tanning practices from PRA users. Thus,

Download English Version:

https://daneshyari.com/en/article/5678653

Download Persian Version:

https://daneshyari.com/article/5678653

Daneshyari.com