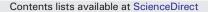
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The keys to healthy family child care homes intervention: Study design and rationale



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ABSTRACT

Background: Obesity is a major public health problem for which early preventive interventions are needed. Large numbers of young children are enrolled in some form of child care program, making these facilities influential environments in children's development. Family child care homes (FCCH) are a specific type of child care in which children are cared for within the provider's own residence. FCCHs serve approximately 1.5 million children in the U.S.; however, research to date has overlooked FCCH providers and their potential to positively influence children's health-related behaviors.

Methods: Keys to Healthy Family Child Care Homes (Keys) is a cluster-randomized controlled trial testing the efficacy of an intervention designed to help providers become healthy role models, provide quality food- and physical activity-supportive FCCH environments, and implement effective business practices. The intervention is delivered through workshops, home visits, tailored coaching calls, and educational toolkits. Primary outcomes are child physical activity measured via accelerometry data and dietary intake data collected using direct observation at the FCCH. Secondary outcomes include child body mass index, provider weight-related behaviors, and observed obesogenic environmental characteristics.

Conclusion: Keys is an innovative approach to promoting healthy eating and physical activity in young children. The intervention operates in a novel setting, targets children during a key developmental period, and addresses both provider and child behaviors to synergistically promote health.

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1. Background

Combating childhood obesity is a public health priority for which preventive interventions are needed. Although recent data suggests an improving weight profile among preschoolers

* Corresponding author. Tel.: + 1 919 681 3030. *E-mail address:* courtney.mann@dm.duke.edu (C.M. Mann). [1], 25% of these children are still overweight or obese [2]. Being overweight in childhood is associated with a wide range of adverse health outcomes [3–12] and young children who are overweight or obese are more likely to be overweight or obese in adolescence and adulthood [13,14]. This evidence, and recent data indicating that obese school aged children reach that status by age five [15], highlights the necessity for intervention before excess weight becomes an issue and while children are still developing important dietary and activity habits.

Child care has been identified as an important setting for obesity prevention efforts [16,17]. Many young children in the US are in some type of non-parental care for a large part of each week [18–20]. Research has shown that child care facilities have substantial influence on physical activity levels during the day [21,22] and provide 50% to 70% of a child's daily calorie intake [23]. Unfortunately, many preschool-age children fail to accumulate the recommended 90–120 min a day of active play [22,24–27], and the foods served often do not meet U.S. Department of Agriculture (USDA) guidelines, particularly for vegetables, whole grains, and milk [28]. Further, personal characteristics of program directors, such as Body Mass Index (BMI), have been shown to be associated with program practices, such as servings of canned fruit, whole grains, and low-fat milk [29]. Therefore, the child care setting and the

efforts. Most child care-based interventions have been programs developed for centers, which may or may not be transferable to other types of child care settings. Family child care homes (FCCH) ¹ are a unique type of child care setting, one that serves approximately 1.5 million children in the US [20]. An FCCH is a small business that operates out of the provider's own home where children are cared for in a more intimate home environment. In FCCH, one provider, who serves as a constant while the children are enrolled in that home, cares for children of all ages. Unfortunately, evidence suggests that time spent in FCCHs during infancy is associated with increased weight at one and three years of age [30], thus making these homes an even more critical target for early childhood obesity prevention efforts.

providers themselves are important targets for intervention

Keys to Healthy Child Care Homes (Keys) is one of the first studies to develop and evaluate an obesity prevention intervention specifically for FCCHs. This innovative intervention is designed to help FCCH providers foster healthy physical activity and eating habits in young children, and thereby promote healthy growth and weight. This manuscript presents the background, rationale, and design, of the Keys study.

2. Methods

2.1. Formative work

To inform the development of the Keys study, the team conducted a survey of local FCCH providers, followed by an abbreviated intervention pilot study. The survey was administered in both an online and in paper format and was completed by 89 providers. Of providers responding to the survey, 57.5% were African American, 40% were White, and 2.5% were Asian. Mean age of providers was 46.2 years and 74% were overweight or obese. While most FCCHs served breakfast (75%), lunch (81%), and an afternoon snack (93%), 35% of these homes served fewer than three servings of fruit and vegetables per day, 46% did not serve whole grains, and 49% served whole rather than reduced fat milk. Additionally, 32% of homes provided less than one teacher-led physical activity session per day.

The intervention pilot study included five providers (80% African American, and all with some college education) and 15 children. Baseline measures showed that nearly all providers had high perceived self-efficacy to provide children with physical activity opportunities and healthy meals; however, assessment of FCCH's physical activity and nutrition environments (using a modified version of the Environment Policy Assessment and Observation (EPAO) [31] tool) showed the need for significant improvements. Children spent about 8.4 h per day in care, 3 h in non-sleeping sedentary activities, but only 20 min of moderate to vigorous physical activity (MVPA) was accumulated [27]. Healthy Eating Index (HEI) [32] scores, calculated from observed dietary intake [33], indicated that the quality of children's dietary intake needed improvement (mean score = 63.8, compared to a score of 80/100, which is considered "good" [34]). Furthermore, four of the five providers were classified as overweight or obese.

The 12-week pilot intervention briefly addressed three proposed program components: Healthy You, Healthy Home, and Healthy Business. The condensed format included a selfassessment, a home visit, a workshop, and a series of contacts from the coach (by mail, email, phone, or web). Providers were highly receptive to the pilot content, indicating that it offered useful information and helpful tools to improve their FCCH business, and provided support for healthy physical activity and nutrition behaviors for both themselves and the children in their care. In addition, providers also reported that the measurement burden was acceptable.

From this formative work, the provider survey and brief intervention pilot, our team gained a better understanding of the issues and topics that resonate with FCCH providers, firsthand knowledge of measuring in the FCCH environment, and a gauge of the feasibility of conducting a multi-component intervention in this novel setting. It quickly became clear that the healthy business portion and in-person workshops, while always important, were very popular. While some measurement logistics were simpler, dealing with one person instead of 3-5 in a child care center, measurement burden had to be more closely assessed and monitored. Part of the solution was to have observers complete the measurements whenever possible (i.e., recording exact times when children went outside) and separating the provider questionnaires into smaller parts given over a few days. We also found that compared to child care centers, FCCH providers had a closer relationship with parents. This created both additional opportunities and challenges for intervention development. We were also able to evaluate acceptability and preference for intervention delivery, estimate the number of children to expect, evaluate the structure of the day, and identify variations in outside and inside spaces that would need to be considered for intervention and measurement purposes.

2.2. Study design

Keys is a two-arm, cluster-randomized controlled trial (RCT) designed to evaluate the efficacy of a nine-month child obesity prevention intervention that promotes (1) providers as healthy role models, (2) physical activity- and nutrition-supportive environments at the FCCH, and (3) healthy business practices. The final sample will include 150 FCCHs and 450 children aged 18 months to 4 years. FCCHs are randomly assigned (1:1) to the

¹ FCCH: Family Child Care Home.

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