

CPC POSTER ABSTRACT 1

Comprehensive Lifestyle Improvement Program For Prostate Cancer (Clipp) Survivors

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Background: Androgen deprivation therapy (ADT) is a mainstay treatment for management of advanced prostate cancer (PCa). ADT has shown to improve survival rates, palliate symptoms and delay cancer progression in men with locally advanced and metastatic PCa. ADT has been associated with adverse events such as loss of libido, insulin resistance, dyslipidemia, diabetes, metabolic syndrome and cardiovascular disease. ADT is also associated with adverse quality of life (QoL) events such as impotence, incontinence, loss of libido and hot flashes. PCa progression has been associated with significant mortality. In 2018, 26,430 men are estimated to die due to PCa, making it the second most common cause of cancer related death in the U.S. Lifestyle Modification (LM) has been associated with improving CVD risk and reducing PCa progression demonstrated in studies by Ornish et al. However, protocol used in these studies was intensive, raising questions regarding applicability of these findings in other groups of patients. The diabetes prevention program is a widely applicable lifestyle modification intervention extensively studied in various populations. This intervention improves CVD risk primarily through its effect on weight reduction. Inflammation and angiogenesis are important processes for PCa progression that are amenable to weight reduction. Given the benefit of ADT in treating advanced PCa, there is an urgent need to find novel strategies to attenuate the cardio-metabolic risk associated with these treatment regimens. The specific aims of this study are:

- 1) To determine feasibility of recruiting, retaining and adherence of 30 PCa survivors on ADT for 24 week LM intervention
- 2) To determine early efficacy of the LM intervention by investigating its effects on anthropometric measurements, metabolic markers, cardio-metabolic risk factors and QoL
- 3) To determine the impact of the LM intervention on inflammation and angiogenesis, important pathways associated with PCa progression

Methods: This is a prospective, single arm, open label feasibility study following 30 men age 40+ with a minimum of a 5 year expectancy, diagnosed with prostate cancer (Stage I to III), who are on androgen deprivation therapy (ADT) for their disease. The intervention will be based on the Diabetes Prevention Program (DPP) that will be adapted to the target population and will be delivered weekly for 16 weeks by a trained health coach. The goal of the intervention will be to promote comprehensive lifestyle change by focusing on various domains like nutrition, physical activity, sleep and stress. Intervention will be delivered using a combination of in-person and telephone based delivery systems based on results of a focus group conducted prior to developing this study. Intervention will be delivered in-person at baseline and every four weeks. For the rest of the weeks, the intervention will be delivered over the telephone. Data Collection will include anthropometric measurements, questionnaires (food frequency, sleep and QoL) as well as collection of urine and serum analysis. This will be carried out at baseline, 12 weeks and 24 weeks. Participants will receive a FitBit as an incentive for participating in the study and to encourage them to track and follow through with their goals.

Results/Conclusion: The Institutional review board as well as other regulatory approvals have been obtained and the study is poised to start recruiting soon.

Phase II Clinical Study of Metformin for Breast Cancer Prevention

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Background: Breast cancer is the most common cancer in women worldwide; risk is elevated in women with higher breast density as well as metabolic abnormalities. Chemopreventive agents such as selective estrogen receptor modulators and aromatase inhibitors are efficacious in breast cancer risk reduction among high-risk women. However, the adverse effects associated with these agents limit their uptake for primary prevention. Development of chemopreventive agents with minimal toxicity and higher tolerability remains a major challenge. Metformin, a widely used anti-diabetic drug, may prevent breast cancer through its favorable modulation of obesity-associated metabolic disturbances. A clinical study of metformin in overweight/obese premenopausal women with components of metabolic syndrome is being conducted at the University of Arizona Cancer Center to assess the potential clinical activity of metformin for breast cancer prevention.

Methods: This is a Phase II randomized, double-blind, placebo-controlled trial. Eligible participants are randomized to receive metformin 850 mg BID (n=75) or placebo (n=75) for 12 months. Anthropometric measures, breast MRI, blood, urine, and nipple aspirate fluid are collected at baseline, 6 and 12 months. Food frequency and physical activity questionnaires are completed at baseline and 12 months. Optional breast core needle biopsies are collected in a subgroup of participants at baseline and at 6 months. The primary objective of this research is to determine the effect of metformin intervention on breast density, assessed by fat/water MRI. Secondary objectives include assessment of the effect of metformin intervention on markers of metabolic disturbances and anthropometric measures.

Results/Discussion: The study successfully reached its accrual target in November 2017. One hundred and fifty-one participants have been randomized and initiated the intervention. As of July 2018, 111 participants have completed intervention, 7 remain active on study, and 33 terminated intervention early. Thirty-six percent of the accrued participants are Hispanics. The average body mass index, waist circumference and waist-to-hip ratio of the accrued participants are 37.8 ± 6.8 kg/m², 110.8 ± 12.4 cm and 0.90 ± 0.07 , respectively. The majority (n=112) provided baseline breast biopsy; with 86 providing 6-month follow-up breast biopsy. The last enrolled participant is expected to complete study intervention in November 2018. Cross-sectional analyses have been performed on the baseline data to evaluate the associations between MRI-derived breast density measures with anthropometric measures and markers of metabolic disturbances. A major strength of MRI for breast density assessment lies in the acquisition of non-compressed breast images/segments. This is especially relevant in our study cohort in accurate assessment of breast density because the compressed breast thickness is greater in overweight and obese women which results in decreased image contrast on mammogram. Results of these analyses will be discussed in the presentation.

CPC POSTER ABSTRACT 2

Are Premenopausal Female Cigarette Smokers Willing to Use Hormonal Contraceptives for Smoking Cessation?

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Background: Compared to men, women are more likely to suffer smoking-related morbidity and mortality and are also the primary source of secondhand smoke exposure in children. Further, despite having comparable levels in motivation to quit smoking, women are more likely than men to relapse from a quit attempt. Accumulating evidence indicates that the menstrual cycle may be undermining quit attempt in premenopausal women. Therefore, identifying innovative smoking cessation interventions designed to the unique needs of premenopausal women is necessary. Depot medroxyprogesterone acetate (DMPA; commonly known as Depo Provera ® by Pfizer) is an injected progesterone-only hormonal contraceptive that temporarily eliminates the menstrual cycle. The goal of this project is to examine the preliminary acceptability of using DMPA as an adjunct treatment to existing smoking cessation interventions.

Methods: An online cross-sectional survey was administered to a convenience sample of women recruited through Facebook advertising who self-reported smoking at least five cigarettes/day. Participants used a 100-point visual analog scale to rate their interest in each of the following smoking cessation interventions: prescription medications, nicotine replacement therapy, in-person behavioral counseling, phone-based behavioral counseling, “cold turkey,” hormone, and injected hormone. Participants were also asked at the end of survey “If this hormone was Depo Provera, the hormonal contraception or birth control shot, does this change your opinion at all?” with an open field for responses as to why this changes opinion (if at all). Descriptive statistics were computed with SAS 9.4.

Results: Survey respondents (n=167) were, on average (\pm standard deviation), 25.6 \pm 6.7 years old and smoked 12.8 \pm 6.7 cigarettes/day. Most were white (91%), non-Hispanic (87%) and had at least a high school education (59%). Overall, participants indicated that their interest in using a “hormone” or an “injected hormone” was either higher or equivalent to other smoking cessation methods (on a 100-point visual analog scale; means (\pm standard deviation): hormone=48.6 \pm 31.9 and injected hormone=36.8 \pm 32.2 versus phone counseling=26.5 \pm 28.2; in-person counseling=28.6 \pm 28.8; prescription medications=38.6 \pm 35.9; “cold turkey”=43.6 \pm 31.9; NRT=46.1 \pm 34.0). Higher values were reported among those who indicated they wanted to quit smoking within three months (n=84; hormone=52.5 \pm 33.4, injected hormone=40.5 \pm 32.6). When asked if opinions changed after knowing the hormone was Depo Provera, most (62%) participants indicated no change in opinion (n=83; 49%) or were more likely to use the hormone (n=22; 13%). Those that reported they were less likely to use the hormone (n=65; 38%) the most common reasons were have heard bad things about Depo Provera (n=18), have had a bad experience with Depo Provera (n=15), does not want to use any type of birth control (n=13), trying to get pregnant (n=7), fear of needles (n=4) and concerns about weight gain (n=3).

Conclusions: This preliminary evidence indicates that premenopausal women smokers will be as receptive to DMPA for smoking cessation as other smoking cessation methods. The most common reason for not wanting to use DMPA is related to misconceptions around safety, as DMPA is one of the safest forms of hormonal contraceptives available for smokers. Future research should explore this innovative technique to improve cessation outcomes in women.

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CPC POSTER ABSTRACT 5

Clinical and Molecular Profile of Renal Cell Carcinoma in Hispanic Americans, Native Americans, and European Americans

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Background: Racial/ethnic minority groups, including Hispanic Americans (HAs) and Native Americans (NAs) have heavier burden of kidney cancer having higher incidence and mortality rate than European Americans (EAs). However, HAs and NAs are underrepresented in clinical and molecular genomic studies of renal cell carcinoma (RCC), the most common type of kidney cancer, and clinical and molecular characteristics of RCC among them are also unknown. Here, we investigated variations in clinical and molecular characteristics of RCC patients.

Methods: A total of 284 patients who were diagnosed with RCC and without prior diagnosis of cancer were included to understand the patients' clinical characteristics. 51 samples were selected to screen for somatic mutations on the VHL gene, and 33 samples were selected for whole transcriptome sequencing analysis.

Results: Compared to EAs, HA and NA patients were diagnosed with RCC at younger age ($P < 0.001$). NA patients had higher body mass index than EA patients, and 77.3% of NA patients were obese. Diabetes was more common in HA (43.0%) and NA (50.0%) patients compared to EA (19.4%) patients. A RCC histologic subtype, clear cell RCC (ccRCC) was more common in HAs and NAs than EAs. Over 90% of HA patients had ccRCC, while only 77.6% of EA patients had ccRCC. HAs had increased odds of diagnosis with ccRCC compared to EAs (OR 2.82, 95% C.I.: 1.24-6.43), but the association was attenuated in adjusted model. Among HAs, older patients were more likely to have advanced stage RCC diagnosis (OR 7.06, 95% C.I.: 1.46-34.11). HAs who used Spanish as their primary language were more likely to have radical nephrectomy rather than partial nephrectomy (OR 5.13, 95% C.I.: 1.23-21.33). Patients who had somatic mutations on the VHL gene, especially patients with pathogenic mutations, which is known to cause von Hippel-Lindau syndrome, were significantly younger than the patients without these mutations (40.6 vs. 58.3, $P = 0.008$). We were able to assign 32 out of 33 patients into molecular subtypes (ccA and ccB). Molecular subtype could not be assigned to one HA patient with high grade and advanced stage ccRCC. Molecular subtype, ccA, was more common in HAs than EAs (64.3% vs. 41.2%), but this difference was not statistically significant. One gene, HABP2, showed evidence of differential expression between HA and EA tumors ($PADJ < 0.05$) and was down-regulated in HA tumors with \log_2 fold change < -2.0 .

Conclusions: HA and NA RCC patients have different clinical and molecular characteristics from EA patients.

Impact: As we move toward precision medicine approach for RCC care, it is necessary to better understand the clinical and molecular characteristics of these underserved population with high kidney cancer burden.

CPC POSTER ABSTRACT 3

Building partnerships with American Indian Communities to Increase Cancer Screening Among Women with Intellectual Disabilities

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Background: Women with intellectual and developmental disabilities (IDD) are less likely than the general population of women to receive recommended breast and cervical cancer screenings. In addition, rates of breast and cervical cancer screenings are lower among American Indian women than they are among White women. Using a community-based approach, with an aim for meaningful community participation, this project will address the specific cancer screening needs of American Indian women with IDD and their networks of support in order to reduce disparities in cancer screening.

Methods: Using qualitative methods, including meeting transcripts, field notes, and reflection, we describe our process for working with a community-advisory board and identifying community research partners. An ecosocial approach has guided the team in its formative work, which centers on identifying structural (e.g. policies, availability of services) and individual (e.g. women with IDD, health care providers) barriers and facilitators to cancer screening.

Results: Arizona is home to 22 American Indian tribes, with varying health infrastructures, cancer control capacities, and ethical guidelines around research collaborations. The co-investigators are faculty in two Arizona universities, with research resources that complement one another. Furthermore, the grant mechanism funding the project is intended to increase cancer research with American Indian communities and provide resources, support, and expertise to assist the development of these collaborations. The research team expanded its capacity for research with American Indian communities by bringing together an advisory board composed of statewide experts in policies and practices related to cancer control, people with IDD, and American Indian health. Meetings with a variety of stakeholders--including researchers who work with American Indians, service providers, and community members--have directed the research team to examine variation in urban and rural communities and consider communities' existing interest and capacity in cancer control.

Conclusions: Once formal research partnerships are established and ethical requirements are met, the research team--including community collaborators--will begin adapting an existing cancer screening education program for women with IDD. In-depth interviews with American Indian women with IDD (N=24), family caregivers (N=24), health care providers (N=24), and leaders in partnering American Indian communities (N=12) will explore barriers and facilitators to cancer screening and the cultural relevance of the program.

Impact: The long-term outcome of this study is to improve rates of breast and cervical cancer screening for American Indian women with IDD by developing culturally relevant programming to address structural and individual barriers to cancer screenings.

Adapting A Multi-Behavioral, Guided Imagery, Mhealth App For Use By Men Of Diverse Racial/Ethnic Groups

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Background: Smoking and its health consequences disproportionately affects socioeconomically disadvantaged populations. In addition, tobacco use co-varies with poor dietary practices and a sedentary lifestyle. A growing body of literature suggests that a multi-behavioral approach, including improving diet and increasing physical activity (PA), may be effective at helping smokers to quit. MHealth apps may be an easy way to deliver such an intervention. The proposed study builds upon our preliminary work in which we developed and evaluated the See Me Smoke-Free (SMSF) mHealth app. The SMSF app was designed to address smoking, diet and physical activity among women smokers. SMSF included a combination of guided imagery (GI) and behavioral strategies for quitting smoking and increasing healthy eating and PA. The use of SMSF was associated with significant reductions in self-reported tobacco use at 3 months (47.6% 7-day abstinence, $p < .001$; and 33.3% 30-day abstinence, $p < .001$).

Methods: In this formative pilot study, we gathered data regarding how to adapt the SMSF intervention for use by men of diverse racial/ethnic groups, including monolingual Spanish speakers. We used a mixed-methods approach with 23 male, racially/ethnically-diverse participants to elicit feedback on how to change the program content, functionality, and user interface. We also explored how to adapt the content and user interface with 9 monolingual Spanish speakers.

Results: Overall, both English- and Spanish-speaking participants rated the app highly. They expressed an interest in using GI for smoking cessation, and saw a benefit to addressing diet and PA while quitting. Qualitative analyses identified specific themes related to use of mHealth programs (e.g., an app is a convenient way to reach people), and those specific to SMSF program content, functionality, and the user interface (e.g., personalization of the user interface, more choice of GI audio files, using icons instead of photos). There were similarities in feedback between English-and Spanish-speakers.

Conclusions: The use of mixed methods and involving the target population during mHealth program development are crucial for developing interventions that are appealing, understandable, and usable. Overall, a diverse sample of male participants liked the SMSF app, and offered helpful suggestions for improving it. Participants indicated that they and other smokers would be very likely to use the SMSF app in the future.

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Development Of A Telephone-Delivered, Guided Imagery Tobacco Cessation Intervention

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Background: Telephone quitlines are an effective and highly scalable way to help individuals quit smoking. However quitlines are an underutilized resource, and do not reach certain segments of the population, including males and racial/ethnic minorities. Guided imagery is a form of mind-body therapy that involves controlled visualization of specific mental images. Studies have shown that imagery training results in significantly increased smoking abstinence rates. Imagery is used by a significant number of racially diverse male and female athletes. We hypothesize that guided mental imagery delivered using the quitline “coaching model” could be an effective and disseminable intervention strategy. In addition, this model may be more readily accepted by underrepresented smokers, and may increase the reach and effectiveness of telephone quitlines. The objective of this study is to develop and test the feasibility of a telephone-based guided imagery intervention versus a standard behavioral intervention for smoking cessation.

Methods: We developed the telephone guided imagery intervention protocols, materials, and companion website with input from the investigative team, quitline personnel, a community advisory board, expert consultants, and 40 focus group and user group participants consisting of male and female, racially- and ethnically-diverse smokers in preparation for a randomized feasibility trial.

Results: We will present findings on our development process, participant characteristics, and how we created and changed the program content and materials for use with a wide range of smokers. Themes and potential changes were identified regarding the definition of guided imagery, the program logo and taglines, definition of quitlines, quit booklet, program introduction, and website. We will share lessons learned, and provide an overview of the guided imagery intervention protocol and program materials. We will also provide an update on participant recruitment activities and accrual.

Conclusion: Using a rigorous formative process, we developed components of a novel quitline intervention prior to use in a feasibility trial. We are currently recruiting and conducting the trial. The results of this study have the potential to improve public health through a novel tobacco cessation intervention, and increase the reach of telephone quitlines by offering an alternative approach to standard services.

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