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Title: The CKD-DETECT STUDY: An RCT aimed at improving intention to initiate a Kidney Health Check in Australian practice nurses

Running title: The CKD-DETECT STUDY

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Introduction The burden of Chronic Kidney Disease (CKD) on the Australian health system is growing. Efforts to reverse this trend have not been successful. **Aim** To evaluate the effectiveness of a targeted asynchronous web based e-learning module on practice nurses' behavioural intentions in relation to opportunistic screening practices for people at risk of CKD

Design Double blinded pre-post interventional randomised control design which is reported using the Consolidated Standards of Reporting Trials guidelines (See Supplementary File 1)

Participants Nurses working in general practice settings in Australia (n=420)

Intervention/Control Participants were randomised to a knowledge based active control or targeted behavioural based intervention which were delivered using asynchronous e-learning modules. The intervention was designed to influence the behavioural constructs of the theory of planned behaviour (TPB): attitude, subjective norm and perceived behavioural control (PBC).

Results Of the 420 participants, we analysed the primary and secondary outcomes for 212 (50.47%) who had full completion data. There were no significant differences in behavioural intention between the intervention and control groups on completion, when controlling for baseline values. However, regression models assessing the relationship between the change in the TPB constructs and behavioural intention on completion for all participants, regardless of study arm, demonstrated a significant effect on change in intention to initiate a kidney health check. Although these changes could not be attributed to the effect of the intervention. On bivariate regression modelling, attitude and PBC accounted for approximately 35% of the explained variance in behavioural intentions and social norm accounted for approximately 33% of the variance. When all TPB constructs were included in a multi-variable regression model, 37% of the variance in intention was explained.

Conclusion A targeted behavioural online intervention was no more effective than a knowledge based online program to improve primary health care nurses' intention to initiate a kidney health check in people at risk of chronic kidney disease.

Relevance to Clinical Practice Collaborative efforts are required by all staff working in general practice to develop models of care to improve screening practices for chronic kidney disease.

What does this paper contribute to the wider global clinical community?

- This paper demonstrated that a targeted behavioural e-learning intervention was no more effective, in changing practice nurses behavioural intention to initiate a kidney health check, than compared to a knowledge based e-learning program
- Future research should evaluate collaborative models of care in general practice aimed at improving screening practices for chronic kidney disease.
- Policy makers should consider introducing funding measures for integrated chronic disease screening by general practice nurses

Keywords: Kidney, primary health care, nursing, screening, behaviour, online learning, randomised control trial, theory of planed behaviour, general practice

1.0 Introduction

The burden of Chronic Kidney Disease (CKD) on the Australian health system is growing. Renal replacement therapy for people with End Stage Kidney Disease (ESKD), the terminal phase of CKD, increased by nearly 47% between 2006 and 2016 (ANZDATA Registry, 2018). This equates to an increase of 37% in total expenditure for CKD, ESKD and their associated therapies, compared to a 14% increase for cardiovascular disease by 2020 (Tucker, Kingsley, Morton, Scanlan, & Dalbo, 2014). These financial estimates do not include the individual cost and personal impact of CKD on peoples' lives.

CKD generally remains asymptomatic until symptoms such as electrolyte disturbances and fluid overload develop, at which stage clinical interventions may not delay the progression of the disease (Hewitt &

Elder, 2014). People whose kidney disease remains undetected have higher mortality rates compared to those who are detected early (Smart & Titus, 2011).

Community (Tracey, Cossich, Bennett, Wright, & Ockerby, 2013), in-hospital (Hewitt & Elder, 2014) and workplace (Mathew et al., 2010) CKD screening programmes have proven effective in increasing its early detection however, they are costly to implement and unsustainable. In contrast, opportunistic screening in the primary health care setting is a more cost-effective and sustainable method for early CKD detection (Howard et al., 2006; Mathew & Corso, 2009). Opportunistic CKD screening is a relatively simple process and consists of identifying people at risk and then initiating a kidney health check (KHC) which includes measuring blood pressure, taking a urine sample for an albumin-creatinine ratio, and a blood test to determine the individuals estimated glomerular filtration rate (Johnson et al., 2013).

This paper reports the results of a parallel group, double blinded randomised control trial that evaluated the effectiveness of a tailored behavioural e-learning intervention compared to a knowledge-based e-learning control in changing the intention of GPNs to initiate KHCs in Australian general practice settings.

2.0 Background

Primary care plays an integral role in the early detection of people with CKD. Opportunistic screening and the early detection of CKD by primary care providers is an essential strategy in reducing mortality and the burden on the health system (Mathew & Corso, 2009; Tracey et al., 2013). However, CKD screening for high risk populations is sub-optimal and there are significant deficits in general practitioners' adherence to

screening practices and evidence-guidelines (Razavian et al., 2011). Consequently, there is a clinical and moral imperative to identify, implement and evaluate methods by which opportunistic screening in the primary health care setting can be improved. General practice nurses (GPNs) are ideally placed to initiate KHCs and collaborate with general practitioners (GPs) in the early detection and management of CKD (Tracey et al., 2013). However, it is not known whether nurses working in primary health settings in Australia already possess the requisite knowledge and skills to undertake these checks. The increasing number of people with CKD means that nurses must achieve and maintain a minimum knowledge level and have the intention to assist in its early detection.

The Theory of Planned Behaviour

The Theory of Planned Behaviour (TPB), an extension of the Theory of Reasoned Action, provides a theoretical framework to objectively measure behavioural intentions as a valid proxy for actual behaviour change (Eccles et al., 2006; McEachan, Conner, Taylor, & Lawton, 2011). According to the TPB, the immediate antecedent of behaviour is intention, which is influenced by three predictor variables: behavioural beliefs (attitudinal), subjective norms (SN) and perceived behavioural control (PBC) (See Figure 1).

Figure 1. Explaining the Theory of Planned Behaviour (Ajzen, 1991, 2011; Godin, Belanger-Gravel, Eccles, & Grimshaw, 2008).

The relationship between intention and behaviour predicts actual behaviour more so than previous behavioural models that used isolated variables, a position supported by systematic reviews in this domain (Eccles et al., 2006; Godin et al., 2008). Changing behaviour requires the

ability to change salient beliefs related to that behaviour. In order to identify why a particular behaviour is or is not performed, it is vital to first identify the extent to which the behaviour is influenced by SN, attitudes and PBC (Ajzen, 1985). Consequently, interventions that directly manipulate variables known to influence intentions to perform a specific behaviour are significantly more likely to change actual behaviour (Webb, Joseph, Yardley, & Michie, 2010).

The CKD-DETECT study

The CKD-DETECT study evaluated the effectiveness of a tailored behavioural asynchronous web based e-learning module (Module two) compared to a case study (knowledge) based module (Module one), on practice nurses' behavioural intentions to perform opportunistic screening practices for people at risk of CKD (see online supplement 1 for a pictorial guide to the two modules).

The study consisted of three aims:

1. To evaluate the effectiveness of an asynchronous web based e-learning module on GPNs' behavioural intentions in relation to opportunistic screening practices in people at risk of CKD.
2. To evaluate the effectiveness of an asynchronous web based e-learning module on GPNs' knowledge about CKD risk factors and screening practices
3. To evaluate GPNs' perceived satisfaction with an asynchronous web based e-learning module

This paper reports the findings of study aim one and its associated hypotheses. Findings related to aims two and three, are reported elsewhere (paper currently under review).

To inform the development of the intervention an elicitation study was conducted to identify the barriers and facilitators to opportunistic CKD screening by general practice nurses (Sinclair, Day, Levett-Jones, & Kable, 2017). The barriers to CKD screening were found to be complex and multi-dimensional and influenced by a combination of social and organizational variables. A constructivist approach (Davidson-Shivers, Rasmussen, & Lowenthal, 2018) was adopted for the design of the intervention which was reported in detail by Sinclair, Levett-Jones, et al. (2017). The intervention was developed with the premise that GPNs may overcome the barriers to CKD screening if they role model or adopt strategies employed by other practices that have effectively implemented chronic disease screening programs previously. The intervention focussed on empowering participants by equipping them with strategies while simultaneously targeting salient beliefs regarding opportunistic CKD screening. Participants in the intervention identified the specific challenges they faced, and programming logic provided a range of practical strategies drawn from two general practices. The two general practices operated under different business models, and had both successfully implemented chronic disease screening programs at minimal cost to the practice.

The intervention initially consisted of a single learning outcome. However, during the development phase a second outcome was added to allow participants the opportunity to position potential solutions suggested in the module, to barriers based on existing challenges they faced in their workplace. Consequently, the learning outcomes for the intervention module were:

1. Identify the challenges that prevent CKD screening in your workplace and;
2. Identify and reflect upon potential solutions to improve CKD screening in your workplace

The intervention consisted of 26 'screens' with various multimedia including animations, videos and links to resources and applications to assist participants in overcoming the barriers. The first seven pages of the intervention targeted attitudinal variables including awareness, prevention, the benefits of early CKD detection and decreasing disease burden. Subjective norms were targeted throughout the intervention with particular focus on the profiled general practices. Factors that influence perceived behavioural control were predominantly addressed during the core barriers section.

The active control was designed and developed to meet two key learning outcomes derived from the Kidney Health Australia - Caring for Australians with Renal Insufficiency Guidelines (Johnson et al., 2013):

1. Identify the major risk factors for developing chronic kidney disease and;
2. Describe the best practice screening method for early chronic kidney disease

It used a case study approach and introduced participants to Mr John Anderson, a 62-year-old who presented to their general practice. It consisted of a total of 16 core pages with each page containing various multimedia and interactive links depending on the content being delivered.

3.0 Methods

A parallel group double blinded randomised controlled trial was used to compare outcomes of a tailored e-learning behavioural intervention to a knowledge based e-learning module as an active control. The trial was registered with the Australian and New Zealand Clinical Trials Registry (Trial ID: ACTRN12617001360303). The trial protocol is hosted with the Australian and New Zealand Clinical Trials Registry at http://www.ANZCTR.org.au/ACTRN12617001360303.aspx No variations were made to the trial design or outcomes after trial commencement. This paper is reported using the Consolidated Standards of Reporting Trials (CONSORT) guidelines (Moher et al., 2012), see supplementary file 1.

Primary hypothesis

Participants randomised to an asynchronous e-learning group will have an increase in behavioural intention of at least 0.3 standard deviation at the conclusion of the program, as measured by the Theory of Planned Behaviour Chronic Kidney Disease Identification and Screening Instrument (TPB-CKDISI), compared with participants randomised to an active control group.

Secondary hypothesis

The indirect theoretical constructs of the TPB (i.e. attitude, SN and PBC) will independently predict the intention of practice nurses to initiate a KHC on people identified as 'at risk' of CKD and/or have a conversation with the treating doctor about the need for a KHC.

Additional study aims

The study also sought to: Evaluate GPNs' perceived satisfaction with an asynchronous web based e-learning module; and evaluate the effectiveness of an asynchronous web based e-learning module on GPNs'

nurses' knowledge about CKD risk factors and screening practices. These outcomes will be reported elsewhere.

3.1 Measurement instruments

All instruments were assessed for face and content validity by a panel of experts from the nursing, primary care and research fields. Prior to launching the study, they were pilot tested by several primary care and renal nurses who assessed the overall structure and content. Minor modifications were made based on feedback from the panel.

The TPB-CKDISI

The Theory of Planned Behaviour Chronic Kidney Disease Identification and Screening Instrument (TPB-CKDISI) was developed to measure the predictor constructs of the TPB (see supplementary file 2). Its construction was informed by the guidelines for the development of TPB questionnaires suggested by Francis et al. (2004) and Ajzen (Ajzen, 2002). For the purposes of this study, the target behaviour was opportunistic screening for CKD which was defined as performing a KHC (i.e. Blood pressure, urinary albumin-creatinine ratio and a blood test for creatinine to determine estimated glomerular filtration rate) on high risk individuals in the general practice setting, without symptoms of kidney disease (Mathew & Corso, 2009). Items were derived from salient beliefs relating to GPNs' screening for CKD (See Table 1) identified in an elicitation study conducted prior to this study (Sinclair, Day, et al., 2017).

TPB questionnaires have the potential to be protracted and complex in nature (Darker & French, 2009). Consequently, a pragmatic decision was made to use one simple yet real world, clinical vignette to guide the instrument:

Bill Smythe is a 62 year old man with a history of hypertension. He smokes a packet of cigarettes a day, his alcohol intake is 6 units per week and his BMI is 32kg/m^2. Bill presents to your practice and tells you he is feeling lethargic and has shortness of breath on exertion.

This scenario was written in this manner to illustrate a presentation that could be associated with a number of potential outcomes. Participants were then asked two direct behavioural intention questions with a binary yes/no response, and to report the degree of difficulty with which the decision was made. Subsequent survey items were direct measures of the TPB predictor constructs attitudes, PBC and SN (Ajzen, 1991). A Behavioural intention score was calculated as the total of the binary response multiplied by the degree of difficulty. The TPB-CKDISI comprised of items related to: attitude (n = 7); subjective norms (n= 4); perceived behavioural control (n= 7); behavioural intentions (n = 2); and decision difficulty (n=2). Four items were reverse scored in order to minimise extreme response and acquiescence bias. A 13 item demographic survey accompanied the TPB-CKDISI. Items assessing the three TPB predictor variables were constructed to measure the interaction between two components, (i) participant's beliefs, and (ii) their corresponding positive/negative judgements. The TPB-CKDISI's internal consistency was considered acceptable if the subscales Cronbach's alpha's were greater than 0.70 (DeVillis, 2003).

Attitudes*:* were assessed using seven paired questions, establishing firstly a measure of behavioural belief strength and then an outcome evaluation about the belief. For example, item five: Performing a KHC improves patient awareness of CKD was paired with item six: Improving the awareness of CKD in patients considered at risk of CKD is […] to me. Response scales were formatted as either unipolar (1 (strongly disagree) to 7 (strongly agree)) or bipolar (-3 (not very important) to +3 (very

important)) depending on whether the construct being measured is unidirectional (i.e. probability) or bidirectional (i.e. evaluation). Higher scores were representative of a stronger intention to perform opportunistic kidney health screening practices. The total attitude score was calculated by multiplying each behavioural belief item by its corresponding outcome evaluation item, and summing the resulting products together. One item was negatively worded and reversed scored as a result. Total scores could range from -147 to 147.

Subjective norms: consisted of an interaction between four injunctive items and four corresponding motivation to comply items. Response scales and scoring were calculated in the same manner as attitudes, with the exception of one question which used a response scale related to approval. For example: Item 25 - General Practitioners where I work would (1 (Always approve) to 7 (Never approve)) of me initiating KHCs; item 26: General Practitioners expectations about me initiating KHCs is (-3 (Very unimportant) to + 3 (Very Important)) to me. No negatively worded questions were presented and total scores ranged from -84 to 84.

Perceived behavioural control: was assessed using seven paired questions, of which three were negatively worded and reverse scored. PBC consisted of an interaction between the strength of a participant's control beliefs with their corresponding perceived power to influence behaviour. For example: Item 39 - Being able to initiate a KHC when I determine the need for it, is part of the role of a Practice Nurse was paired with item 40. Initiating a KHC is […] for me Response scales were formatted as either unipolar (1 (strongly disagree) to 7 (strongly agree)) or bipolar (-3 (very difficult) to +3 (very easy)), with total scores ranging from -147 to 147. The total PBC score was calculated by multiplying each control belief item by its corresponding power to influence item, and summing the resulting product together.

Table 1: Salient beliefs used for the TPB instrument (Adapted from Sinclair, Day, et al. (2017)) [a] Medicare Benefits Schedule *Negative beliefs

3.2 Scoring of outcomes

Behavioural intentions (BI): Two items directly assessed participant's BI to (i) independently initiate a KHC; and (ii) have a conversation with a General Practitioner about initiating a KHC. For analysis BI was assessed using the two direct measures in addition to the sum of the two direct measures to provide an overall direct behavioural intention score (named BI sum). A fourth measure assessed predictor constructs of the TPB: attitude, SN and PBC. Participants responded yes or no in response to the question asking if they would perform the behavior given the scenario presented to them. For each item participants were also asked to rate, on a seven-point Likert scale (ranging from very difficult to very easy), how difficult they would find performing each of the behaviours. To determine participant's direct behavioural intentions their yes/no responses were multiplied by their corresponding level of difficulty.
One participant had a missing Attitude Score, as a result of one missing behavioural belief item response. The missing behavioural belief response was imputed using the average of other subjects with similar attitude belief responses (Andridge & Little, 2010). A behavioural belief response that was within 2 units of the participant's response was considered similar.

3.3 Sample size calculation

Sample size calculation was performed using Stata version 14 (Statacorp, College Station, TX). Based on *a priori* power calculations, 110 participants per group were needed to detect a medium effect size (effect size [d] 0.3)

with 80% power and 5% type I error rate. This calculation assumed a baseline/completion correlation of 0.6.

Study sample

The study sample consisted of general practice nurses currently working in an Australian general practice. Approximately 63% of Australian general practices employ a practice nurse (Australian Medicare Local Alliance, 2012). A practice nurse is any nurse practitioner, registered (equivalent of baccalaureate qualified) or enrolled nurse (equivalent of licensed practical nurse) who is employed by a general practice service.

3.4 Participants, recruitment, randomisation and treatment allocation

Participants were recruited via social media (Facebook and Twitter) and primary health care network newsletters and where approved, email lists across Australia between October, 2017 and April, 2018. Each announcement contained a link to the study website which contained a series of statements for potential participants to click as part of the inclusion/exclusion and consent process. The core inclusion criterion was that participants were nurses who had worked in an Australian general practice setting within 12 months of enrolling. An inability to read English was the only exclusion criterion. Potential participants clicked the submit button to register for the study and were then allocated to study groups (1:1) by an independent research assistant using a web-based randomisation schedule. The randomisation schedule used a permuted block randomisation with blocks of randomly varying size, stratified by rurality and years of experience (< 10 years or 10+ years). Group allocation was concealed from those conducting data analysis to avoid ascertainment bias. An email was then sent to participants with a

hyperlink, depending on their randomisation, to either the active control arm or the intervention arm. Baseline outcome and demographic data was not collected prior to randomisation, as this was logistically and practically difficult. Participants were blinded to treatment allocation to avoid selection bias. Reminder emails were sent out on three separate occasions during the recruitment period. All participants who completed the program received a continuing professional development certificate and were entered into a draw for one of three AU$100.00 gift cards.

3.5 Ethics and procedure

The institutions human research ethics committee provided ethical approval for the study (H-2016-0394). Consent was recorded after participants clicked the submit button. Participants randomised to the intervention group completed two online survey instruments, the pre-CKD knowledge instrument and the pre-TPB-CKDISI. Participants scoring < 75% (n=102/105) on the pre knowledge instrument undertook module one (A knowledge based e-learning module), and repeated the CKD knowledge questionnaire on completion. They then proceeded to module two, regardless of knowledge score. Participants scoring ≥ 75% (n=3/105) on the pre knowledge instrument proceeded directly to module two. On completion of module two, participants completed two online survey instruments, the post-TPB-CKDISI and the LSAe-L instrument. Participants in the active control group completed the same instruments as the intervention group, the Pre-CKD knowledge questionnaire and the TPB-CKDISI. They then, regardless of scores, undertook module one only. On completion participants completed the post-CKD knowledge instrument, the Post TPB-CKDISI and the LSAe-L instrument. Data were collected from October, 2017 until May, 2018 when sufficient participants had completed the study.

4.0 Data Analysis

Data analysis was conducted using SAS 9.4 (SAS Institute Inc., Cary, NC, USA). A p value of ≤ 0.05 was considered to be statistically significant. Participant demographic characteristics were summarised by mean (standard deviation), median (interquartile range) and frequency (percentage) separately for the intervention and control groups. A separate Analysis of Covariance (ANCOVA) was conducted for each of the outcome variables, to determine whether there were any differences in these outcomes between the intervention and control group. The ANCOVA models consisted of the completion value as the dependent variable and the baseline and intervention group variables as the independent variables. Baseline adjusted differences between groups are presented, together with 95% confidence intervals, and p-values. Cohen's d are also provided to give a standardised effect size of the difference between the two groups. A Cohen's d value of < 0.2, was considered a small effect size, 0.2- 0.5 a medium effect and 0.5-0.8 as a large effect size (Sawilowsky, 2009). Linear regression was used to assess the relationship between baseline BI and the three indirect TPB constructs (the secondary aim). Changes in the TPB constructs (between baseline and completion) were also assessed for association with the BI at completion using linear regression. These regression models also included factors predicted to be associated with intention (intervention group, age, rurality, nursing years, primary health nursing years and bulk billing practices). Prior to creating the BI outcome variable, we established that a significant moderate positive linear relationship existed between the two BI outcomes. Cronbach alphas were calculated for all instrument subscales.

Population

The first population of interest were those that were randomised and completed both the baseline and final outcome surveys (the completers' population). The second population, a modified intention to treat population (MITT), included participants that were randomised and completed and baseline demographic and outcome data.

Missing data

Our primary analysis was of the completers' population. For the MITT population, we compared participant demographics between those with missing completion data using t-tests and Chi-Square tests for categorical variables. Missing completion data was then imputed in 30 completed datasets using chained regression equations. ANCOVA regression models were used to estimate the treatment effect in each imputed dataset, and results were pooled across imputed datasets using Rubin's method (Rubin, 1987). Baseline outcomes and demographic variables that were found to be statistically significantly associated with missing completion outcomes were included as auxiliary variables in the multiple imputations of completion outcomes.

Figure 2: Study flow chart (adapted from Moher et al. (2012))
[a]Completed = all pre and post instruments completed.

5.0 Results

Figure 2 demonstrates the flow of participants through the trial. Of the 420 participants registering for the study, 199 were randomized into the control group, and 221 to the intervention group. Of those 420, 86 never accessed the survey link, 15 withdrew and 319 accessed the survey link. Of the 15 withdrawn, 8 of those participants had demographic data and baseline data. Of the 319 participants that accessed the survey, 301 had

complete baseline data, 212 had complete data. Participants who withdrew from the study did not complete any of the post-instruments. Consequently, 212 participants were analysed in the completers group and 309 in the MITT group.

Participant characteristics

Table 2 presents the characteristics of participants that completed both surveys by intervention and control group. Consistent with the demographics of nurses in Australia, the majority of respondents were female. Both groups had similar distributions between demographic variables. Forty-three percent of participants had accessed prior CKD education, and the two main modes were face to face workshops and journal articles. Fifty-seven percent of participants had no previous CKD education.

Table 2: Participant characteristics

Primary hypothesis

There was a significant positive linear relationship between BI outcome one (initiate a KHC) and BI outcome two (initiate KHC conversation) [r^2 0.54 ($p < 0.0001$) pre-intervention and r^2 0.48 ($p < 0.0001$) post-intervention]. Table 3 presents the means of the baseline and completion outcomes, the estimated intervention effect size derived utilising ANCOVA with a 95% C.I., the respective p-value and the Cohen's d value for the completers group. As the means and medians were close in values, only the mean is reported. There were no significant differences between the intervention and control groups on completion. Both groups appear to have had similar increases in outcomes assessed from baseline to completion. The lack of effect size was confirmed with all Cohen's d values less than 0.2. The internal reliability of the TPB-CKDISI was

satisfactory with Cronbach alphas for subscales Attitude (α 0.868), SN (α 0.800), and PBC (α 0.860) demonstrating the predictive power to explain variance in intention.

Table 3: Mean scores of direct and indirect TPB measures at baseline and completion of 'completers' population (n=212)

Sensitivity data

The MITT dataset, consisted of the 309 participants that had valid baseline outcome data (i.e. had completed all baseline surveys). Table 4 reports the intervention effect size for the MITT. Similarly to the completers group, there was no significant effect of the intervention on any of the outcomes.

Table 4: ANCOVA results from MITT analysis population (n=309).

Exploratory analysis: Secondary hypothesis

Table 5, consists of the results of five linear regression models that were conducted to assess the relationship between baseline BI sum, and the indirect TPB domains: attitude, SN and PBC. The first model contained only the covariates: age, rurality, overall nursing years, primary health nursing years and whether their workplace bulk-billed and were selected as they were the factors most to likely influence behavioural intention. It was conducted to allow for comparisons in the amount of variance that was explained by the addition of each TPB domain. For the remaining four models, the independent variables were each of the three indirect TPB domains separately, and then lastly combined. The model with only the covariates accounted for 4% of the variation in BI, while attitude, SN and PBC models accounted for approximately 12%, 8% and 24%

respectively. When all baseline constructs were included, approximately 26% of the variation in BI sum was explained.

Table 5: Regression models assessing the relationship between the TPB constructs and BI sum at baseline (n=309); *Covariates included intervention group, age, rurality, nursing years, primary health nursing years and bulk billed. Regression coefficients for covariates are not included in the output since they are not of interest for this aim.

Similarly, Table 6, assesses the relationship between BI Sum at completion and changes in the indirect TPB domains: attitude, SN and PBC, from baseline to completion. The outcome of each model was BI Sum at completion. For the remaining models, the independent variables were the change in the indirect TPB domains, separately and then combined. Each model was also adjusted for participants' BI Sum baseline scores, age, rurality, overall nursing years, primary health nursing years and whether their workplace bulk- billed. Results demonstrated that when compared to the covariates only model and the other single construct models, change in attitude and PBC had the greater influence on the outcome, completion BI Sum, indicated by the higher r^2 value and lower AIC value for these models. The change in attitude and PBC models each accounted for approximately 35% of the variance; while the SN model accounted for approximately 33%. When all TPB indirect domains were included in the model, 37% of the variance was explained. Analysis using multiple imputation for the MITT population obtained similar results.

Table 6: Regression models assessing the relationship between the change in the TPB constructs and BI sum at completion (n=212) *Covariates for all models included Intervention Group, BI Sum at baseline, age, rurality, nursing years, primary health nursing years and bulk billed.

6.0 Discussion

This study evaluated the effectiveness of an asynchronous web based e-learning module on GPNs' behavioural intentions in relation to opportunistic screening practices in people at risk of CKD. The control and intervention groups did not differ significantly in the change from baseline for any of the study outcomes. These findings were replicated in the MITT analysis. Therefore the primary hypothesis was not supported. The lack of an intervention effect was not likely to be due to poor acceptance of the e-learning intervention as user satisfaction (to be reported elsewhere) was identified as acceptable. Completing the study had an equivalent effect on all participants. Linear regression demonstrated a statistically significant change in the TPB predictor constructs in relation to the BI sum. The lack of difference between study groups may have two plausible explanations. Firstly, all participants were exposed to e-learning modules that were designed using a framework to develop high engagement-high quality online learning experiences. The use of provocative and relevant scenarios in both modules, despite targeting specifically different phenomenon (i.e. Module 1: Knowledge & Module 2: Behaviour) may have contributed to this change. A lower fidelity control may have yielded different results. The second explanation could be related to more powerful determinants that influence behaviour. The actual act of performing a KHC requires specific clinical and behavioural decisions that will be influenced by other factors before it can be performed. At any stage these factors, some of which are beyond the volitional control of GPNs, could negatively influence direct intention. These factors include: the complexity and variation in work practices, culture, fee for service funding models, the absence of chronic disease screening MBS item numbers, collaboration and relationships in

primary care (McInnes, Peters, Bonney, & Halcomb, 2017b; Oelke, Besner, & Carter, 2014).

The expansion of the GPNs role in Australia is inhibited by the lack of MBS item numbers to cover services that can be managed by GPNs. Internationally, fee-for-service models in some countries cover wellness visits and chronic care management services that can be delivered independently by primary health care nurses(Ganguli, Souza, McWilliams, & Mehrotra, 2017). Despite the Australian governments (2018) introduction of practice nurse incentive payments, some GPs do not see this as a payment for service to meet population and service demands (McInnes, Peters, Bonney, & Halcomb, 2017a). Consequently, the current Medicare system should be reviewed with consideration of payment reform and the re-introduction and expansion of claimable MBS item numbers for services that can be rendered exclusively or collaboratively by GPNs. Existing MBS items limit GPNs' scope of practice and ability to practice autonomously and may encourage some general practices to focus on income generation at the expense of preventative care and screening services.

The introduction of a dedicated MBS item number for integrated chronic disease screening for the early detection of vascular and related diseases, including CKD, is required (National Vascular Disease Prevention Alliance, 2015). An integrated approach to the detection of chronic disease recognises the interaction between risk factors and multiple chronic diseases and would be a cost effective approach to disease specific screening practices. In the absence of a dedicated MBS item number for chronic disease screening, more focus may be required on building collaborative working relationships between GPNs and GPs in primary care.

The secondary hypothesis examined the indirect theoretical constructs of the TPB, namely attitude, SN and PBC. We hypothesised that they would independently predict the intention of GPNs to conduct a KHC on people identified as 'at risk' of CKD and/or have a conversation with the treating doctor about the need for a KHC. These were analysed as BI sum due to their positive linear relationship. The study's findings supported the secondary hypothesis.

Regression models were used to assess the relationship between the TPB predictor variables and BI Sum for all participants (n=309) who completed the TPB-CKDISI at baseline. When all baseline TPB predictor variables were included, 26% of the variation in the BI sum was explained. The relationship between BI Sum and the changes in all predictor variables at completion was significant in all completers (n=212) regardless of the study arm to which they were randomise. When the relationship between the changes in predictor variables were included in the regression model, approximately 37% of the variance was explained. Attitude (p = 0.0004), subjective norm (p = 0.0171) and perceived behavioural control (p = 0.0005) accounted for 35%, 33%, and 35% of the variance in BI Sum, respectively and were all significant predictors of intention. The lack of significant differences between groups suggests that exposure to the study, regardless of study arm, positively influenced the BI of participants. This explained variance is consistent with previous reviews that have reported between 33.7% (Conner & Sparks, 2005) and 40% (Godin & Kok, 1996) for predicting health care practitioners (HCP) clinical intentions.

This is one of few studies that has measured the utility of e-learning to influence HCP behaviour change in chronic disease screening and is the first to use a social cognition approach in attempt to manipulate some of the factors that influence the initiation of KHCs by GPNs. This study confirms that there is insufficient evidence to support the effectiveness of

wholly asynchronous e-learning programs to influence HCPs' clinical behaviour (Sinclair, Kable, Levett-Jones, & Booth, 2016). While e-learning approaches can improve access to educational resources by GPNs, they may not be the ideal mode of delivery to influence change in clinical behaviour.

7.0 Limitations and future research

A number of factors must be considered while interpreting the results of this study. The TPB-CKDISI was developed using the guidelines reported by Francis et al. (2004) and Ajzen (2002) for this study The use of a self-reported instrument may have influenced the association between the BI Sum and predictor constructs secondary to social desirability and/or recall bias. The survey items for this entire study, including the knowledge and satisfaction measures not presented in this paper, numbered 157 both pre and post in total. Consequently response burden, may have influenced the findings. Using an objective behavioural measure would have strengthened this design. However this was considered impractical and costly given the number of participants required to power the study adequately. Alternatively, the use of the TPB afforded a more practical way in which to measure behavioural intentions as an immediate antecedent to GPNs' behaviour. While participants were blinded to treatment allocation to avoid selection bias, the nature of the intervention may have meant they were able to determine to which study arm they had been randomised. Finally, the response rate and incomplete responses mean that results may not be representative of GPN's across Australia and should be interpreted with caution.

HCP decision making is a complex process influenced by multiple factors. Future research should consider the environmental, workplace and cognitive processes underlying clinical decision making with particular focus on shared decision making. In doing so, future interventions can be developed that are more sensitive to the factors that influence HCP behaviour. Consideration should also be given to addressing and evaluating the redesign of general practice models of care to better incorporate GPNs' scope of practice and utilise their skills and knowledge. Currently a substantial variance in GPNs' roles and responsibilities exists across workplaces (Norful, Martsolf, & Poghosyan, 2017). This variation in Australia, may be due to GPs unfamiliarity with GPNs' scope of practice. This creates a tendency for nursing roles to be task orientated, to support GPs, rather than fully utilising their knowledge and skill set (Halcomb, Salamonson, Davidson, Kaur, & Young, 2014; McInnes et al., 2017b). Given the impact of the study overall on BI sum, in particular the predictor variables of attitude and PBC, future interventions should investigate ways to improve the volitional control of GPNs to initiate a KHC. Despite being ideally positioned to lead CKD screening initiatives, it is apparent from this study that considerable barriers factors still remain that prevent them from providing this service. Considering that existing research has described a disconnect between GPs understanding of the GPNs' role and their actual scope of practice, it would be prudent to measure the effectiveness of interventions that use inter-professional education approaches to promote better collaboration and improve shared decision making. This is all the more important given that HCP behaviours are considered habitual when conducted in a stable context and that entrenched behaviours are more difficult to change (Gardner, 2015; Godin et al., 2008).

Professional relationships between nurses and doctors in general practice have been cited as problematic (Pullon, 2008). Collaborative practice underpins the delivery of safe and effective health care regardless of the health setting. Future research should consider collaborative, team based interventions that require practice nurses and general practitioners to work collaboratively to develop models of care that focus on improving chronic disease screening and management practices in the absence of current claimable Medicare item numbers.

Finally, an alternate approach to attempting to influence the intention and/or behaviour of GPNs is to consider public health campaigns to increase screening rates. Health promotion campaigns are effective strategies which positively influence health behaviour (Noar, Bell, Kelley, Barker, & Yzer, 2018). Future research could consider targeted campaigns to extend the focus from HCPs and on to the community identifying whether they possess risk factors for CKD. People with risk factors can then be encouraged to approach their primary care provider regarding the need for a kidney health check.

8.0 Conclusion

With a renewed national focus on primary health care, practice nurses play a crucial role in health promotion and opportunistic screening practice in the community. This study has demonstrated that a targeted high engagement – high quality asynchronous e-learning program was unable to change general practice nurses intention to initiate a KHC and/or have a conversation with a GP about the need for a KHC when compared to a knowledge based e-learning program. However, the relationship between behavioural intention and the changes in all predictor variables at completion were significant overall for practice nurses in the study. This suggests that participation in the study and

engagement with study materials on the topic, regardless of the allocated study arm contributed to changed behavioural intention.

9.0 Relevance to Clinical Practice

The scope and autonomy with which GPNs deliver screening and health promotion services is limited by the conditions of their employment and the context of their workplace culture and practices (Hoare, Mills, & Francis, 2012).

Clinical decision making is multifaceted process, particularly those related to screening and diagnosis (Godin et al., 2008). Behaviour change within the context of this present study was influenced by multiple factors including activity based funding models, medically defined roles, unfunded time versus competing funded priorities, business rules and the absence of an MBS item number for chronic disease screening. These factors and personal characteristics vary widely among and between general practice settings and are known barriers to optimising the GPN role fully in primary care (Oelke et al., 2014).

In addition, GPs may not realise the full capabilities of GPNs in the primary care setting with some struggling with the opportunities collaborative practice affords (McInnes, Peters, Bonney, & Halcomb, 2015; McInnes et al., 2017b). Understanding the GPN's role and full scope of practice will promote collaboration and optimise their role in the primary care workforce to improve chronic disease outcomes for patients and providers alike (Oelke et al., 2014).

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Attitude	Subjective Norm	Perceived Behavioural Control
Early detection & treatment	Approval of GPs & patients	Existing screening protocols
Reduction of disease burden	Activity based funding models (MBS[a] items)*	Presence of known risk factors
↑ awareness of CKD	Medically defined roles	Relationship with patient
↑ prevention of CKD	The business*	Unfunded time vs competing funded priorities*
Imposition on time & competing clinical priorities*		Lack of MBS item number*
Threat of patient harm (Stress and financial)*		Impact on patient*
Knowledge &/or skill deficit*		Practice business rules*

Table 1: Salient beliefs used for the TPB instrument (Adapted from Sinclair, Day (18))
[a] Medicare Benefits Schedule *Negative beliefs

Participant Characteristics		Control (n=107)	Intervention (n=105)	Total (N=212)
Age (years)	n	107	105	212
	mean (SD)	47.08 (12.28)	46.95 (10.88)	47.02 (11.58)
	median (Q1, Q3)	49 (37, 56)	48 (38, 56)	49 (38, 56)
Gender	Male	1 (0.9%)	2 (1.9%)	3 (1.4%)
	Female	106 (99%)	103 (98%)	209 (99%)
Language	English	96 (90%)	101 (96%)	197 (93%)
	Other	11 (10%)	4 (3.8%)	15 (7.1%)
Job Title	Enrolled Nurse	2 (1.9%)	5 (4.8%)	7 (3.3%)
	Endorsed Enrolled	13 (12%)	6 (5.7%)	19 (9.0%)
	Registered Nurse	86 (80%)	91 (87%)	177 (83%)
	Nurse Practitioner	4 (3.7%)	2 (1.9%)	6 (2.8%)
	Other	2 (1.9%)	1 (1.0%)	3 (1.4%)
Number of Primary Health Nurses	n	107	105	212
	mean (SD)	3.8 (4.78)	6.1 (20.11)	4.94 (14.56)
	median (Q1, Q3)	2 (1, 5)	3 (2, 4)	3 (2, 4)
Number of GPs	n	107	105	212
	mean (SD)	7.33 (5.84)	7.7 (5.26)	7.51 (5.55)
	median (Q1, Q3)	6 (3, 10)	7 (4, 10)	6 (4, 10)
Number of patients registered in practice	n	107	103	210
	mean (SD)	4811.14	12297.3	8482.92
	median (Q1, Q3)	2000 (600,	4500 (1000, 9000)	3000 (1000, 7000)
Hours per week	n	107	105	212
	mean (SD)	30.59 (10.2)	28 (10.47)	29.31 (10.39)
	median (Q1, Q3)	32 (24, 38)	28 (21, 37)	30 (23, 38)
Years Nursing	n	107	105	212
	mean (SD)	23.78 (30.71)	22.95 (14.87)	23.37 (24.15)
	median (Q1, Q3)	22 (7, 33)	23 (12, 32)	22.5 (8.5, 32.5)
Primary Health Nurse	n	107	105	212
	mean (SD)	7.94 (8.38)	7.99 (7.96)	7.96 (8.16)
	median (Q1, Q3)	5 (2, 11)	5 (2, 10)	5 (2, 11)
Rurality	major cities\inner regional	84 (79%)	81 (77%)	165 (78%)
	outer regional\ remote	23 (21%)	24 (23%)	47 (22%)
Bulk Billed	No	61 (57%)	72 (69%)	133 (63%)
	Yes	46 (43%)	33 (31%)	79 (37%)
Prior CKD Education	No	64 (60%)	57 (54%)	121 (57%)
	Yes	43 (40%)	48 (46%)	91 (43%)
Delivery Mode				
Face to Face	No	83 (78%)	78 (74%)	161 (76%)
	Yes	24 (22%)	27 (26%)	51 (24%)
E-Learning Education	No	85 (79%)	91 (87%)	176 (83%)
	Yes	22 (21%)	14 (13%)	36 (17%)
Journal Article Education	No	68 (64%)	67 (64%)	135 (64%)
	Yes	39 (36%)	38 (36%)	77 (36%)
Pharmacy Rep Education	No	82 (77%)	84 (80%)	166 (78%)
	Yes	25 (23%)	21 (20%)	46 (22%)

Participant		Control	Intervention	Total
Webcast	No	100 (93%)	96 (91%)	196 (92%)
	Yes	7 (6.5%)	9 (8.6%)	16 (7.5%)
Other Education	No	97 (91%)	97 (92%)	194 (92%)
	Yes	10 (9.3%)	8 (7.6%)	18 (8.5%)

Table 2: Participant characteristics

	Baseline		Follow-up				
	Control mean (SD) (n=107)	Intervention mean (SD) (n=105)	Control mean (SD) (n=107)	Intervention mean (SD) (n=105)	Intervention Effect Size (95%CI)	*p*	Cohen's d
Direct B.I. Outcome 1: Initiate Kidney Check	4.64 (2.47)	4.14 (2.6)	5.92 (1.43)	6.02 (1.11)	0.21 (-0.11,0.53)	0.1955	0.04
Direct B.I. Outcome 2: Kidney Check Conversation	4.43 (2.47)	3.59 (2.73)	5.25 (1.7)	4.98 (1.65)	0.01(-0.38,0.41)	0.940	0.10
B.I. Sum	9.07 (4.25)	7.73 (4.61)	11.17 (2.83)	11 (2.25)	0.24(-0.35,0.84)	0.424	0.04
Predictor Constructs							
Attitude	92.84 (28.32)	89.6 (32.98)	101.73 (31.81)	97.8 (30.28)	-1.73(-8,4.53)	0.586	0.13
Subjective Norm	36.79 (24.24)	37.43 (20.31)	41.62 (25.1)	39 (20.78)	-3.1(-7.36,1.15)	0.152	0.12
PBC	47.36 (41.95)	41.3 (40.26)	59.06 (45.13)	58.73 (38.19)	4.43(-2.8,11.66)	0.228	0.01

Table 3: Mean scores of direct and indirect TPB measures at baseline and follow-up of completers population (n=212)

	Intervention Effect Size (95%CI)	*p*
Indirect B.I. Outcome	0.19(-13.6, 13.98)	0.9780
Direct B.I. Outcome 1: Initiate Kidney Check	0.16(-0.13, 0.44)	0.2793
Direct B.I. Outcome 2: Initiate Kidney Check Conversation	0.04(-0.31, 0.38)	0.8312
B.I. Sum	0.22(-0.32, 0.76)	0.4236
Attitude Score	-0.8(-7.04, 5.45)	0.8020
S.N. Score	-2.06(-6, 1.89)	0.3067
P.B.C. Score	2.96(-3.93, 9.85)	0.3996

Table 4: ANCOVA results from MITT analysis population (n=309).

Model	Variable	Estimate	SE	*p*	r^2	AIC
1. Covariates Only*		.	.	.	0.0446	919.696
Model 1 +Attitude	Attitude	0.0525	0.0080	<.0001	0.1221	883.574
Model 1+SN	SN	0.0584	0.0115	<.0001	0.0781	898.684
Model 1 +PBC	PBC	0.0546	0.0055	<.0001	0.2435	837.548
Model 1+ Attitude, SN and PBC	Attitude	0.0134	0.0093	0.1508	0.2579	835.640
	SN	0.0163	0.0118	0.1700		
	PBC	0.0459	0.0066	<.0001		

Table 5: Regression models assessing the relationship between the TPB constructs and BI sum at baseline (n=309); *Covariates included intervention group, age, rurality, nursing years, primary health nursing years and bulk billed. Regression coefficients for covariates are not included in the output since they are not of interest for this aim.

Model*	Variable	Estimate	SE	*p*	r^2	AIC
1. Covariates Only		.	.	.	0.3106	333.436
Model 1 + Attitude Change	Attitudes	0.0213	0.0059	0.0004*	0.3525	322.140
Model 1 + SN Change	SN	0.0219	0.0091	0.0171*	0.3297	329.484
Model 1 + PBC Change	PBC	0.0186	0.0052	0.0005*	0.3510	322.633
All	Attitude Change	0.0132	0.0068	0.0533	0.3700	320.317
	SN Change	0.0117	0.0093	0.2130		
	PBC Change	0.0107	0.0061	0.0829		

Table 6: Regression models assessing the relationship between the change in the TPB constructs and BI sum at follow-up

Behavioural intention can be explained mathematically as a sum of the three predictor variables: $BI_B = A_B + SN_B + PBC_B$ Where BI = Behavioural intention $_B$ = the behaviour A = Attitude SN = Subjective Norm PBC = Perceived Behavioural Control	
Attitude towards behaviour (AB)	Beliefs influenced by knowledge, experience and values which reflect participants' positive or negative perceptions about performing a target behaviour, in this case opportunistic CKD screening;
Subjective norms (SN)	Participants' perceptions of social pressure about performing the target behaviour, and their motivation to conform to such pressure;
Perceived behavioural control (PBC)	The degree of control the participant perceives they have, over the factors that promote or prevent the target behaviour. So while participants may have the intention to initiate CKD screening they also need to have the opportunity, resources and support in order to act on that intention.

Figure 1. Explaining the Theory of Planned Behaviour [13-15].