Title: A Study to Evaluate the Feasibility and Acceptability of a Diabetes Survival Skills + DSS+) Training Intervention for Incarcerated Persons Transitioning to the Community (TTC)

Approved February 24, 2022 No expiration

No NCT Number available for this protocol

UCONN
UNIVERSITY OF CONNECTICUT

DATE: February 24, 2022

TO: Louise Reagan, Ph.D., ANP-BC, APRN
Nursing Instruction and Research

FROM: RCS IRB Office/dsb.
FWA# 00007125

RE: Protocol #: H17-006, "A Study to Evaluate the Feasibility and Acceptability of a Diabetes Survival Skills + (DSS+) Training Intervention for Incarcerated Persons Transitioning to the Community (TTC)"
Please refer to the Protocol # in all future correspondence with the IRB.
Re-approval Period: From: **February 24, 2022 To: No Expiration Date**

The Institutional Review Board (IRB) re-approved this protocol on January 22, 2021. The research presents no more than minimal risk to human subjects and qualifies for expedited approval under category #8(c): Continuing review of research previously approved by the convened IRB as follows: where the remaining research activities are limited to data analysis.

Since this study expired on January 21, 2022, the IRB acknowledges that: a) no participants have been enrolled since the expiration date; b) no participants will be enrolled until the study has been re-approved; and c) no research has been conducted since the expiration date.

All investigators of the University of Connecticut are responsible for complying with the "Responsibilities of Research Investigators" attached to this letter.

Modifications: If you wish to change any aspect of this study, such as the procedures, the consent forms, the investigators, or funding source, please submit the changes in writing to the IRB using the Amendment Review Form (IRB-3). All modifications must be reviewed and approved by the IRB prior to initiation.

Audit: All protocols approved by the IRB may be audited by the Post Approval Monitor.

Please keep this letter with your copy of the approved protocol.

Attachments:
1. Validated IRB-2
2. "Responsibilities of Research Investigators"

Office of the Vice President for Research
Research Compliance Services
438 WHITNEY ROAD EXTENSION, UNIT 1246
STORRS, CT 06269-1246
PHONE 860.486.8802
FAX 860.486.1044
compliance.uconn.edu

UCONN
UNIVERSITY OF CONNECTICUT

Internal office use only:

Full Board __ Expedited __
Protocol #

(IRB-1) Protocol Application for the Involvement of Human Participants in Research
Institutional Review Board, Research Compliance Services

SECTION I: General Information

Nature of Study: (Place an "X" in the column. Check only one.)	**X**	Faculty Research		Graduate Research
		Dissertation		Undergraduate Research
		Masters Thesis		Staff Research

Study Title: A Study to Evaluate the Feasibility and Acceptability of a Diabetes Survival Skills + (DSS+) Intervention for Incarcerated Persons Transitioning to the Community (TTC):

Study Objective (2-3 sentence summary of study): _ A study is proposed to determine the feasibility and acceptability of a Diabetes Survival Skills intervention training with and without a support group for incarcerated persons transitioning to the community. Feasibility will include limited efficacy testing to examine the effect of the DSS+ intervention on diabetes knowledge, self-efficacy, outcome expectancies, and diabetes related distress.

PI, Student Investigator, Correspondent Information:

	Principal Investigator (PI)	**Student Investigator** (only for Student Initiated Research)	**Correspondent** (primary point of contact for correspondence, if applicable)
Name (First, Last, Degree):	Louise Reagan PhD		Louise Reagan
Department:	Nursing		Nursing
Mailing Address:	231 Glenbrook Road Storrs, CT		231 Glenbrook Road Storrs, CT
Preferred Phone #:	860-874-5644		860-874-5644
Emergency Phone # (Required Full Board, More than Min. Risk only):	860-874-5644		
Preferred E-Mail Address:	Louise.reagan@uconn.edu		Louise.reagan@uconn.edu

Very Important: Complete and attach the Appendix A form to list all UConn key personnel engaged in research and other non-UConn investigators.

Section II: Collaborating Institutions/Facilities and Other IRB Reviews

Will the research be conducted only at Storrs and/or the five regional campuses, School of Law, or School of Social Work with no involvement of a collaborating institution? ___ **Yes** X **No (If yes, skip to Section III)**

Collaborating Institutions with a Collaborative Agreement with UConn-Storrs

UConn has formal agreements with the University of Connecticut Health Center (UCHC), Hartford Hospital (HH) and the Connecticut Children's Medical Center (CCMC) that authorize one IRB to take the lead with some research protocols. This decision is made by the IRBs involved, but the PI may request which IRB he/she prefers to be the IRB of record. See the IRB website for additional information. If you are collaborating with one of the institutions listed below, place an X in the appropriate cell to indicate which institution, based on the preponderance of expected enrollment, you are requesting serve as the IRB of record or that independent IRB approval will be sought from each applicable site. If you request that UConn-Storrs be the IRB of record, place an X in the appropriate cell.

Institution Name	% to be enrolled/consented	Requested IRB of Record	Independent IRB Review
UConn Health Center			
Hartford Hospital			
Connecticut Children's Medical Center			
UConn – Storrs			

Provide additional comments as needed:

If the PI, Student Researcher or other Key Personnel has an affiliation/appointment with an Institution listed above, please explain:

_____

Other Collaborating Institutions/Facilities

If you are collaborating with other sites, provide the name of each institution/facility (e.g. other university, K-12 school, nursing home, tribal affiliation, etc.) and describe the type of involvement of each institution (e.g. recruitment, enrollment/consenting, study procedures, follow-up, data analysis). Indicate if IRB approval/site permission is attached (indicate yes, no, or pending). You will need to obtain IRB approval from every collaborating institution that has an IRB before you can initiate research there.

Note: tabbing out of the bottom right cell will insert another row if needed.

Name of Institution	Describe Involvement	IRB Approval/Site Permission Attached?
CT Department of Corrections	The proposed research will be conducted at two male Connecticut State correctional facilities- Osborne and Cybulski Correctional Institutions.	Connecticut Department of Corrections Research Advisory Council (RAC), (pending IRB approval)

Provide additional comments as needed: Received administration approval from Colleen Gallagher, Director, Quality Assurance, Health& Addiction Services at State of Connecticut - 10/2016.

If the PI, Student Researcher or other Key Personnel has an affiliation/appointment with an Institution listed above, please explain:

_____

International Research

Will any aspect of the study take place outside of the United States? ___ **Yes** X **No**
(If yes, complete table below)

NOTE: You may need to obtain IRB approval in the country where the research is taking place and/or a Federal-wide Assurance with the Office of Human Research Protections (OHRP). Please see the IRB website for additional information.

List Location(s)	**Name of Collaborating Institution/Facility**	**Describe Involvement**	**IRB/Ethics Approval and/or Site Permission Attached?**

Provide additional comments as needed:

If the PI, Student Researcher or other Key Personnel has an affiliation/appointment with an Institution listed above, please explain:

_____

SECTION III: Funding

It is the responsibility of the Principal Investigator to notify the IRB via an Amendment (IRB-3) or at Re-Approval, on an IRB-2 form if the funding source changes in any way.

Funding Source: (Place an "X" in the column next to the funding source.)		Departmental Funds		Human Rights Institute
	X	External (including subawards)		Research Incentive Account
	X	Faculty Grants (Large/Small)		Faculty Start-Up Funds
		Graduate School DDF or EE Award		Investigator Out-of-Pocket
		Office of Undergraduate Research Award		Unfunded

For Internal, UConn Funded Studies:

If the research is supported either in whole or in part by internal funds (Internal Program Support, Office of Undergraduate Research, Research Incentive Accounts, etc) one COMPLETE copy of each grant application (if applicable) must be included with this application.

Name of Internal/UConn Funding Source:	Scholarship Facilitation Fund, OVPR

Principal Investigator**:**	Louise Reagan, PhD
Grant Title (if applicable and if different from protocol title):	Diabetes Survival Skills + (DSS+) Intervention for Incarcerated Persons Transitioning to the Community (TTC)_: A Pilot Study
KFS Account Number (if known and only applicable for Faculty Large and Small Grants funded by Internal Program	
Proposal Number (if applicable, e.g.	
Grant Status (i.e., pending/awarded):	Awarded $2,000 2/10/2017

Provide any additional comments as needed:

Note: If there is more than one funding source, copy the table format and add the additional funding source.

For Externally Funded Studies:
If the research is supported either in whole or in part by external funds (federal, state or private), one COMPLETE copy of each grant application or contract must be included with this application.

For each funding source, please identify the following:
NOTE: If the PI on the grant/contract is not the PI on this IRB protocol, submit an e-mail with this application in which the PI who is receiving the grant acknowledges use of this protocol under the grant**.**

Name of Funding Source I (if UConn is the recipient of a subaward, list the institution providing the funding then list the primary source of funds):	American Nurses Foundation
Principal Investigator of /Grant**:**	Louise Reagan PhD
Contract/Grant Title: (if different from protocol title)	Feasibility of a Diabetes Survival Skills Intervention for Incarcerated Persons Transitioning to the Community
KFS Account Number:	
OSP Proposal Number:	
Grant/Contract Status: (i.e., pending/awarded)	$5,000 Pending receipt of IRB approval 9/1/2017

Will funds from this contract/grant be awarded to an individual or institution (via a PSA or subcontract) that will be engaged in human participant research? ___ **Yes** X **No**
If yes, indicate the name of the institution: ___University of Connecticut _____
Provide any additional comments as needed:

Name of Funding Source II(if UConn is the recipient of a subaward, list the institution providing the funding then list the primary source of funds):	
Principal Investigator of Contract/Grant**:**	

Contract/Grant Title: (if different from protocol title)	
KFS Account Number:	
OSP Proposal Number:	
Grant/Contract Status: (i.e., pending/awarded)	

Will funds from this contract/grant be awarded to an individual or institution (via a PSA or subcontract) that will be engaged in human participant research? ___ **Yes** X **No**
If yes, indicate the name of the institution: _____
Provide any additional comments as needed:

Note: If there are more than two funding sources, copy the table format and add the additional funding source.

SECTION IV: Conflict of Interest (only required for externally funded research)

At the time of proposal submission to the Office for Sponsored Programs (OSP), all investigators and key personnel are required to submit a Significant Financial Interest Review Form to OSP. For more information, please go to the Conflict of Interest Committee website, http://www.compliance.uconn.edu/conflict.cfm.

Is any investigator listed on this protocol required to submit the follow-up form, *"supplemental"* Significant Financial Interest Review Form? ___ **Yes** X **No**

If yes, please identify each individual:
_____

SECTION V: Human Participants

Place your responses BELOW, not within, the box containing each item's description.

How many participants will be enrolled?
If you are enrolling more than one population describe the total enrollment for each. Note: Participants are generally considered to be 'enrolled' when they sign the consent form or have gone through an oral consent process. Therefore, be sure to account for attrition in your enrollment number.

There are over 18,000 incarcerated and transitioning to community men, women and adolescents living under the Connecticut Department of Corrections system. It is estimated that the number of inmates with Type 1 or 2 diabetes exceeds 400. For the PIs dissertation research (H12-303), she recruited, consented, enrolled and interviewed 124 incarcerated persons in approximately four months. There was a large pool of incarcerated person with diabetes who requested participation in the prior study. The PI anticipate this same response but the sample size will be limited by the eligibility criteria of being within 6-9 months of release from prison.

For the proposed feasibility study, ninety-six participants (12 per group) will be enrolled to participate in Diabetes survival skills (DSS) education sessions in facilities designated as a treatment (Cybulski Correctional) and control group (Osborn Correctional). Forty-eight participants in the treatment facility will have the option to participate in a support group 6 weeks after the completion of the DSS sessions. The DSS plus a support group is referred to as DSS+. Participants who enroll in the study are not required to join the support group.
To allow for a control group in this feasibility study, the PI will recruit 96 participants from two male facilities. Forty-eight persons will be enrolled from the treatment facility (Cybulski correctional institution) and forty-eight from the designated control facility (Osborne Correctional). Persons housed in these prisons have received or are completing an assigned sentence, may be directly released from the facilities to the community or half-way houses. One facility houses slightly less inmates but both have similar ethnic, and racial distributions. Nurses in the two facilities are contracted to provide nursing care to the inmate population and function under the same policies and proceduresAlthough there is no evidence to support the exact number of persons for Group patient education, the Center for Medicare and Medicaid has recommended 2-20 participants with an average of 10 participants (Health Care Finance Administration, 2000). Attrition rates for diabetes self-management education (DSME) programs vary as do the number of sessions for various group DSME models. Attrition rate for individual and group DSME has been reported from 0-50% (Newman, Steed, & Mulligan, 2004). In consideration of attrition, twelve participants will be enrolled in each of the four sessions.

To further reduce attrition rates, the PI will send appointment reminders to participate in a sealed envelope via the Connecticut Department of Corrections (CTDOC) mail system. This process will be accomplished in cooperation with the CDOC liaison.

1. Health Care Finance Administration, rules and regulations. Fed Regist 65:83129–83154, 2000
2. Newman, S., Steed, L., & Mulligan, K. (2004). Self-management interventions for chronic illness. The Lancet, 364(9444), 1523-1537.

If applicable, how many potential participants will be screened?

When screening procedures are conducted as part of the consent process, participants that fail to screen will be counted as being enrolled in the study.

Interested participants will be screened for eligibility by the PI until the sample is achieved.
It is estimated that the PI will screen 100-150 potential participants to achieve a sample of 96.
Prior to scheduling a meeting with the potential participant, the PI will request that the DOC designee (Jennifer Benjamin RN, MSN, DNP, Correctional Health Services Program Director), review the sick slip requests of persons interested in participating to confirm that the inmate can be released form their units. Some inmates (potential participants) who have a higher DOC assigned security classification are not allowed to participate in groups. If interested potential participants do not meet the security classification, the PI will follow the DOC procedure for notifying participants who do not meet the DOC classification criteria. Confirming security classification is a routine procedure in the prison performed prior to all inmate activities and does not confer additional risk to the potential participants.
After this procedure, The PI will proceed with contacting the inmate, scheduling an appointment to determine eligibility using the screening script (Attachment 4), obtain informed consent and begin study procedures.

Individuals will be eligible to participate if they have Type 1 or 2 diabetes, are of male gender, any race, or ethnicity and: 1) are age 18 and older, 2) are able to speak, and understand English, 3) are

incarcerated and within 6-9months of being released from prison, and 4) have a CTDOC classification designation that allows them to participate in group sessions.

Participant Population(s):
Describe the participant population(s) including gender, ethnicity, age range, income, level of education, and language spoken.

Of studies examining the health status of incarcerated persons in CT (Lewis, 2005; McGuire, Rosenheck & Kasprow, 2003), the average age of inmates is young, approximately 34 years, although there is a growing elderly population; the majority of inmates are male (91%), unmarried (86%) and of minority race (45% African-American, 27% white, 26% Hispanic, 2% other).
The PIs prior research with 124 participants from the same population and setting found similar results to that of that Lewis (2005) and McGuire et al. (2003) with the exceptions of age and race of the participants. The participants in the PI's study (Reagan, Walsh, & Shelton, 2016)(H12-303) were older and included a greater number of white participants. (see table I) Females were recruited for the prior study but with low enrollment likely due to the ratio of males to females incarcerated in the Connecticut Correctional system. The PI is conducting this pilot study research in two male facilities so females will not be recruited for the pilot. The PI intends to seek a distribution similar to what is reported here but recognizes that this may not be feasible.

Table 1*Sociodemographic and Clinical Characteristics of Incarcerated Persons with Diabetes (N = 124)*

Characteristic	N	%	M	SD
Gender				
Male	116	93.5		
Female	8	6.5		
Age			47.32	9.46
Race				
White, Non-Hispanic	42	33.9		
Hispanic	29	23.4		
Black	53	42.7		
Marital Status				
Single/Divorced/ Separated	101	81.5		
Married/Partner	23	18.5		
Education				
< High School GED	34	27.4		

McGuire, J., Rosenheck, R. A. And Kasprow, W.J. (2003). Health status, service use and Costs among veterans receiving outreach services in jail or community settings. Psychiatric Services, 4, 201-207.

Reagan, L. , Walsh, S.J., Shelton, D. (2016). Relationships of illness representation, diabetes knowledge, and self-care behaviour to glycemic control in incarcerated persons with diabetes, International Journal of Prisoner Health, Vol. 12 Iss: 3, pp.157 - 172 Int J Prison Health. 12;12(3):157-72. doi: 10.1108/IJPH-04-2015-0010.

Recruitment:
Describe the recruitment process including *who* will recruit, *when* and *where* recruitment will take place and *how* participants will be identified and recruited (e.g., direct recruitment by study team in person, on the phone, by mail/email/internet, random sampling, referrals from other participants, snowball sampling and/or healthcare providers). Attach copies of all advertisement/recruitment materials for IRB review including phone scripts, web postings, newspaper advertisements. If recruiting at off-campus sites, written permission and/or local IRB approval may be required.

The PI will recruit all study participants. The PI will recruit participants similar to the method used for her dissertation research(H12-303). The recruitment process for the prior study was effective and has been used for other research projects in the prison. For the PIs dissertation research, she recruited, consented, enrolled and interviewed 124 incarcerated persons in approximately four months. There was a large pool of incarcerated person with Type 1 and 2 diabetes who requested participation in the prior study.

1. Indirect Recruitment: Recruitment flyer
The inmate patient will be informed by way of a recruitment flyer(Attachment1) of the procedure for communicating to the researcher his interest of learning more about and/or participating in the study. Therefore, Inmate patients will self-identify if they wish to hear more about or participate in this study. The recruitment flyer pending CDOC approval will be posted to request inmate patient participation with this study. The flyer will be posted in English and Spanish at a fifth grade reading level. Although exact numbers are not known, CDOC administration believes that there are inmates who speak and understand English but may read Spanish more easily than English. At the request of CDOC, fliers will be available in English and Spanish.

Possible areas for posting the flyer include inmate housing units, inside and outside the medical exam rooms used for the Diabetic or Chronic care clinic, near the location of the medication line and where diabetic inmate patients check their finger stick blood glucose levels. Areas for posting will be determined with input from CDOC Research Advisory Council (RAC), CDOC administration and research liaison. As stated on the recruitment flyer, the inmate who is interested in participating in the study will be asked to:
1. Write in on a “sick slip” request his/her name and the words “Diabetes Study”
2. Place the sick slip in the request box.

This “usual “procedure for requesting a sick visit or visit with the nurse or provider is similar in each facility. Upon IRB approval, the PI will work with the CDOC designated research liaison to refine this recruitment strategy. Usually, sick slips are sorted and prioritized by the CMHC nurse. The nurse who is triaging the sick slip requests will place those slips indicating a request for information about the “diabetes study” in the PI’s mailbox. This mailbox will be located in the facilities medical record department or in some other designated location as determined by CDOC.
The PI will pick-up the “Diabetes study” sick slip requests from medical records at least twice weekly and arrange to meet each of the inmates who completed this request. In the PI’s prior experience with interviewing inmates (H12-303), the correctional officer (CO) stationed at the facilities medical clinic arranged for the inmates to come to the medical clinic for meetings with the student. This procedure worked well, was arranged by CDOC administration and likely will be used for this research study.

Similar to a previous experience with interviewing inmates, a private yet secure exam or office space will be used to complete recruitment, screen and obtain informed consent.

2. Direct Recruitment: In Person
It is more than likely that some inmates are unable to read. In order to provide information about this study and thereby not exclude inmates who cannot read the flyer, the PI will arrange with the CDOC to be available in the waiting area of the medical clinics during some sessions of the diabetes chronic care clinic. The PI will meet with inmates interested in hearing more about or participating in the study in a private area to speak. The PI would read the information on the recruitment flier to the interested inmate. If interested in participating in the study, the PI would either 1. Record the inmates name and arrange to meet at a later time or 2. Proceed with screening.

Additional plans to enhance the above described recruitment strategies are described here.
1. Prior to the study, the PI will provide a letter (Attachment 2) that includes a short description of the study to the CMHC Director of Nursing. If agreeable, the Director of Nursing will send via email the letter with the description of the study to the CMHC nurses. The PI will be available to come to the nursing supervisor meeting to describe the study. The PI will ask the nurses to direct patient inmates who inquire about this diabetes study to complete a "sick slip request" as outlined in recruitment strategy number 1.

Special Population(s):
Identify any special participant population(s) that you will be **specifically targeting** for the study.

Check **all** that apply: (Place an "X" in the column next to the name of the special population.)		Minors	**X**	Economically/Educationally Disadvantaged
	X	Prisoners		Members of the Armed Forces
		Pregnant Women/Neonates		Non-English Speaking
		Decisionally Impaired		Individuals Living with AIDS/HIV
		UConn Students		Other (Please identify):
		UConn Employees		

UConn Students or Employees:
Are you recruiting students who are in a class you teach or for which you have responsibility? ___ **Yes** X **No**
Are you recruiting employees who report to you? ___ **Yes** X **No**

If 'Yes," explain why this population is necessary to the study and indicate precautions taken by the researchers to minimize potential undue influence or coercion:
_____
_____
_____
_____

SECTION VI: Drugs/Devices, Genetic Testing, Radiation and Biological Samples

Drug/Device Use
Does the study involve the use of any of the following (check all that apply)?

- An FDA approved drug or medical device ___ **Yes** X **No**
- An investigative/unapproved drug, supplement or medical device ___ **Yes** X **No**
- A non-medical device ___ **Yes** X **No**
- A proprietary product ___ **Yes** X **No**
- A biological agent ___ **Yes** X **No**

If yes, please complete the **Drug/Device Supplemental Form** (IRB-1A) and attach it to this application.

Biological Samples
Does the study involve the use of biological samples?
(Either banked or prospectively obtained) ___ **Yes** X **No**
If 'Yes,' you will need to obtain approval from the Biosafety Officer before the study can be initiated. Please attach a copy of the approval letter if approval has already been granted from the BSO.

Genetic Testing
Does the study involve the genetic testing of biological samples? ___ **Yes** X **No**
If yes, please complete the **Genetic Testing Supplemental Form** (IRB-1B) and attach it to this application.

Radiation or Radioisotopes
Does the study involve the use of radiation or radioisotopes? ___ **Yes** X **No**
If yes, you will need to obtain approval from the Radiation Safety Officer before the study can be initiated. Please attach of copy of approval letter if approval has already been granted from the RSO.

SECTION VII: Research Plan

Purpose
State the reason for the study, the research hypothesis, and the goals of the proposed study as related to the research question(s).

Decades of research involving community dwelling and ethnically diverse persons with diabetes support the effectiveness of various tailored and culturally relevant group/individual models of DSME/S for improving diabetes knowledge [1,2,3] self-care behavior(SCB)[2] and metabolic control [2,4] and stimulating participation in proactive risk reduction.[5] Many inmates, are typically not included in this. It is unknown whether the evidence based DSME strategies used in the general community such as with discharge from the hospital to home are feasible, acceptable and effective for best supporting the transition of incarcerated persons in their continued DSM into the community. For example, one study reported prisoners, at seven days' post prison release, had higher rates of hospitalization for short-term diabetes complications and lower extremity amputations compared to matched controls.3 Interviews with recently released prisoners revealed significant stress post-release related to not knowing how and when to take insulin.[6] In another study, respondents reported lack of knowledge regarding what foods to eat, how to control their blood sugar, take medications, or access health care.

[7] Diabetes Survival Skills such as taking medication, administering insulin, managing diet, blood glucose monitoring, sick day and hypo- and hyperglycemia management are considered basic skills needed for survival by all patients with diabetes. At a minimum, incarcerated persons transitioning to the community have a critical need for DSS.. The purpose of this study is to examine the feasibility and acceptability and preliminary efficacy testing of a 6-session Diabetes Survival Skills(DSS) intervention to incarcerated persons with diabetes witin 6-9 months of transitioning to the community. In one facility, the Diabetes Survival Skills sessions will be followed by a support group(DSS+) and feasibility of the support group will be examined.

Research questions: The general research questions for this feasibility study were developed based upon Orsmond and Cohn[8] proposed questions to guide a feasibility study.

1. How appropriate are the data collection procedures and outcome measures for the intended population and purpose of the study?
2. Are study procedures and intervention suitable for and acceptable to participants?
3. Does the research team have the resources and ability to manage the study and intervention?
4. Does the intervention show promise of being successful with the intended population?

1. The primary aim is to evaluate feasibility of the experimental protocol.

Hypotheses: H1) Recruitment: 96 eligible persons will consent to participate in the study within 2 months after the onset of recruitment H2) Attendance/Attrition: 90% of enrolled participants will attend and complete the 6-session DSS Training. H3) Engagement: 75% of enrolled participants' will document responses to work-book questions, record blood glucose and if applicable associated diet or activity information. H4) Intervention implementation: The intervention will be delivered according to the DSS timeline (Figure1) and session outline. H5) Skill proficiency: Participants will return demonstrate how to use the blood glucose meter, insulin pen (as indicated), and blood glucose log, and other skills specific to DSS session 1-6.

2. The secondary aim of this study is to determine participants' acceptability of the program and program and study materials including the perspective in participating in the intervention using focus groups.

3.**The tertiary aim** is to explore the preliminary efficacy and the short-term effect of the DSS intervention on diabetes knowledge (Spoken Knowledge in Low Literacy for Diabetes) Appendix, self-efficacy (Self-care of Diabetes Inventory Confidence Subscale), and distress (Problem Areas in Diabetes Scale) at baseline, immediate post-program and 6 weeks post-DSS program, or immediately before release if release from prison is less than 6 weeks post-DSS program.

4. Evaluate the feasibility of a post-session support group (one facility) by documenting potential problems with scheduling, participation, and engagement.

The overall goal of this study is to use the results to inform a pilot study of the effect of a DSS (Diabetes Survival Skills) on clinical (e.g. glycemic control and Cardiovascular measures), psychosocial (e.g. Diabetes Related Stress, Quality of Life), and behavioral (e.g. self-care and adherence) post-release outcomes and to explore the feasibility of adding a support group to the DSS intervention (DSS+).

Reference

1. American Diabetes Association (2016). Standards of medical care in diabetes-2016 abridged for primary care providers. Clinical Diabetes. 33, 97–111. doi: 10.2337/dc12-s011

2. Brunisholz, K. D., Briot, P., Hamilton, S., Joy, E. A., Lomax, M., Barton, N., . . . Cannon, W. (2014). Diabetes self-management education improves quality of care and clinical outcomes determined by a diabetes bundle measure. Journal of multidisciplinary healthcare, 7, 533.
3. Chrvala, C. A., Sherr, D., & Lipman, R. D. (2015). Diabetes self-management education for adults with type 2 diabetes mellitus: A systematic review of the effect on glycemic control. Patient education and counseling.
4. Powers, M. A., Bardsley, J., Cypress, M., Duker, P., Funnell, M. M., Fischl, A. H., . . . Vivian, E. (2015). Diabetes Self-management Education and Support in Type 2 Diabetes A Joint Position Statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. The Diabetes Educator, 41(4), 417-430.
5. Fan, L., & Sidani, S. (2009). Effectiveness of Diabetes Self-management Education Intervention Elements: A Meta-analysis. Canadian Journal of Diabetes, 33(1), 18-26. doi: http://dx.doi.org/10.1016/S1499-2671(09)31005-9
6. Thomas, E. H., Wang, E. A., Curry, L. A., & Chen, P. G. (2016). Patients' experiences managing cardiovascular disease and risk factors in prison. Health & justice, 4(1), 1.
7. Salem, B. E., Nyamathi, A., Idemundia, F., Slaughter, R., & Ames, M. (2013). At a Crossroads: Reentry Challenges and Healthcare Needs among Homeless Female Ex-Offenders. Journal of Forensic Nursing, 9(1), 14–22
8. Orsmond, G. I., & Cohn, E. S. (2015). The Distinctive Features of a Feasibility Study Objectives and Guiding Questions. OTJR: occupation, participation and health, 35(3), 169-177.

Introduction
Provide a clear and succinct summary description of the background information that led to the plan for this project. Provide references as appropriate and, when applicable, previous work in animal and/or human studies. Provide previous UConn protocol number, if applicable.

Although there are conflicting reports of diabetes prevalence in prison ranging from 5-11%[1,2], diabetes disproportionately affects African American and Latino persons who represent over half of incarcerated population[3,4] (Figure 1). Typically, inmates come to prison from socially disadvantaged communities and return to the same communities [5]. And the release rate of prisoners into the community is increasing [6,7] Stabilizing mental and physical illnesses such as diabetes and engaging inmates in self-care prior to re-entry will not only improve the health and well-being of the inmate but also has the potential to improve overall health and decrease health disparities in that community.

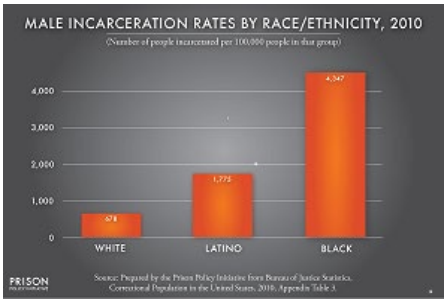

Figure 1

Community based persons with diabetes perform 95% of their care, and make numerous and often complex decisions to self-manage diabetes.[8,9] Engaging persons with diabetes in DSM is critical to improving diabetes and health outcomes[10,11]and as a result DSME and ongoing support (DSMT/S) has become the cornerstone of diabetes care [9]. Decades of research involving community dwelling

and ethnically diverse persons with diabetes supports the effectiveness of various tailored and culturally relevant group/individual models of DSMT for improving diabetes knowledge[12,13,14], self-efficacy and empowerment[15], self-care behavior(SCB)[13] and metabolic control[11,12] and stimulating participation in proactive risk reduction[16]. Yet, research of this nature involving vulnerable incarcerated persons with diabetes planning to transition to the community is essentially non-existent[17].

Additionally, Incarceration is a disruptive life event known to be associated with multiple stressors and threats to self-care [17] Many inmates have chronic stress from pre-incarceration issues such as substance abuse, [19,20] untreated or serious chronic health conditions [2], prior physical abuse, intimate partner violence, and/or repeated incarceration [7] Psychological, emotional, and related behavioral factors are important for self-managing diabetes, mental health and addiction disorders. Research shows that most inmates who recidivate don't have the proper coping mechanisms that will allow them to deal with life outside of prison[21]. Cognitive dysfunction, often present in this population, can adversely affect memory and executive function [22], and impair diabetes self-management (DSM) abilities.

The American Association of Diabetes Educators has identified transitions such as transferring to a new provider, moving from inpatient to outpatient, moving into a correctional facility or having a change in insurance status as critical times to providing DSME. Areas of focus for a transition may include identifying needed adaptions in DSM, providing support for independent skills and self-efficacy, establishing follow-up plans with providers and family or other support systems and assisting with facing challenges affecting the usual level of self-management.[9]

Moving from the correctional facility to the community is also a time of transition. Incarcerated persons with diabetes transitioning to the community will need to navigate the health care system to obtain needed appointments and medications, and cope with other competing demands of findings housing and employment. Enhancing self-care skills and making plans for reentry is critical for incarcerated person with diabetes because they have been deskilled (e.g. limited selection in food selection and meal time, not allowed to administer insulin or measure glucose independently and on their schedule) as a result of prison. Or they may have been newly diagnosed with diabetes in prison and likely have not been independently performing key SCBs specifically Diabetes Survival Skills such as taking medication, administering insulin, managing diet, blood glucose monitoring, sick day and hypo- and hyperglycemia management.

Interviews with recently released incarcerated persons revealed significant stress post-release related to skill deficits such as not knowing how and when to take insulin[23]. Even with access to primary care post-release, hypertension blood pressure and diabetes A1C targets of formerly incarcerated persons were not maintained at six months' post-release[24]. The combined effects of comorbidity, life history and the prison environment can potentially affect an incarcerated persons perceived control, motivation, and self-efficacy for diabetes self-care and thus the ability to plan and engage in self-care especially during transition phases.

In preliminary research with incarcerated persons with diabetes in the Connecticut Department of Corrections(CDOC), the PI found significant diabetes knowledge deficits related to hypo/hyperglycemia, key SCBs, allowed within the prison, were not being performed, and lower personal control beliefs about their ability to affect diabetes outcomes were associated with lower A1C or worse metabolic control. [17] Thirty-five percent of the sample (n=124) were diagnosed with diabetes while in prison and likely had no experience with self-managing diabetes in the community.

Furthermore, A1C levels (a measure of metabolic control) were above the American Diabetes Association's recommended target of 7% for most participants.[10,17] Findings from the PI's post-program evaluation of the CDOC's pilot of a two-year prison adapted eight session Group Medical Appointment (GMA) (combined group DSME/S and medical care)[25] suggested that some inmates had health beliefs or perceptions not congruent with good DSM and limited diabetes knowledge [26].

The findings, the combined with the knowledge that approximately 95% of inmates are released back into the community[27] highlight the critical need and moral imperative for developing evidence based DSMT/S that address the health needs of vulnerable incarcerated persons and engage them in DSM particularly diabetes survival skills prior to their reintegration into society. The DSS Intervention is based on the National Standards of Diabetes Education, the PI's prior research and preliminary work with incarcerated person with diabetes, and is grounded in the Information-Motivation-Behavioral Skills [28,29]model of DSM.

Theoretical Framework

The proposed study is guided by the Information-Motivation-Behavioral skills (IMB) model [28, 29] of health behavior change. The IMB model posits that a person needs accurate information about the health behavior, personal and social motivation to act on the information, and the behavioral skills to correctly perform the behavior [28] The IMB model has been used widely to inform health behavior change interventions for improving adherence to treatment among persons with HIV and more recently to enhance diabetes knowledge, motivation and behavioral skills for Latinos with diabetes. In a study with Latinos with diabetes, Osborn et al. [29] found that diabetes knowledge (knowledge), fatalistic attitudes (personal motivation), and social support (social motivation) were significant direct predictors of diabetes self-care and through behavior were related to glycemic control.

The proximal outcomes of interest for the current study include diabetes knowledge (information), outcome expectances (personal motivation), self-efficacy (behavior skills), peer support (evaluated in one facility only) (social motivation) and diabetes related distress which may or may be mediated by peer support and self-efficacy [30]. Given the small sample size, efficacy testing is limited. The goal is to continue the DSS or DSS+ intervention training and follow releasees out into the community to examine distal outcomes of the IMB model including adherence, and glycemic control.

Table II. IMB based DSS Intervention components

Construct	Operationalized	How Provided
Information	Diabetes Knowledge	• Interaction with APRN/PI expert in providing DSME. Focus on Diabetes Survival Skills. • Selected Low Literacy Patient Education Pamphlets from the Partnership to Improve Diabetes Education (PRIDE)study [31] (Attachment 3)
Motivation	Support Group (for two groups) Outcome Expectancies	• APRN/PI to facilitate using motivational interviewing techniques. • Discussion of benefits of self-care
Behavioral skills	Self-efficacy	• Workbook Questions based on Diabetes Survival Skills found in the

		Diabetes Education Prompt Pack [32] (AADE,2016). • Return Demonstration/Simulation: Performing Finger sticks for Blood Glucose Monitoring, Insulin Administration, Documentation in Log Book, Food Selection, Hypoglycemia management.
Possible Mediator	Diabetes Related Distress	• Review results of PAID survey at beginning of study to obtain an estimate of the level of distress among participants. Add stress and diabetes to DSS program if needed. • End every session with the three cycles of the 4-7-8 relaxation breath

1. Lorber, D. L., Chavez, R. S., Dorman, J., Fisher, L. K., Guerken, S., Haas, L., & Wakeen, B. (2013). Diabetes management in correctional institutions. Diabetes Care, 36 (SUPPL.1), S86-S92. doi:10.2337/dc13-S086.
2. Wilper, A. P., Woolhandler, S., Boyd, J. W., Lasser, K. E., McCormick, D., Bor, D. H., & Himmelstein, D. U. (2009). The health and health care of US prisoners: Results of a nationwide survey. American Journal of Public Health, 99(4), 666-672. doi:10.2105/AJPH.2008.144279
3. Wang, E., & Green, J. (2010). Incarceration as a key variable in racial disparities of asthma prevalence. BMC Public Health, 10(1), 290.
4. Dumont, D. M., Allen, S. A., Brockmann, B.W., Alexander, N. E., & Rich, J. D. (2013). Incarceration, community health, and racial disparities. Journal of Health Care for the Poor and Underserved, 24(1), 78-88. doi:10.1353/hpu.2013.0000.
5. National Research Council (2014). The growth of incarceration in the united states: exploring causes and consequences. Committee on causes and consequences of high rates of incarceration, Western, T. B. & Redburn, S., eds. Committee on law and justice, Division of Behavioral and Social Sciences and Education. Washington DC:The National Academies Press.
6. Cuellar, A. E. & Cheema, J. (2012). As roughly 700,000 prisoners are released annually, about half will gain health coverage and care under federal laws. Health Affairs, 31(5), 931-938. doi:10.1377/hlthaff.2011.0501.
7. West, H., Sabol, W., & Greenman, S. (2010). Prisoners in 2009. Bureau of Justice Statistics, NCJ 231675.
8. Pearson, M. L., Mattke, S., Shaw, R., Ridgely, M. S., & Wiseman, J. S. H. (2007). Patient Self-Management Support Programs: An Evaluation. Chrvala, C. A., Sherr, D., & Lipman, R. D. (2015). Diabetes self-management education for adults with type 2 diabetes mellitus: A systematic review of the effect on glycemic control. Patient education and counseling.
9. Powers, M. A., Bardsley, J., Cypress, M., Duker, P., Funnell, M. M., Fischl, A. H., . . . Vivian, E. (2015). Diabetes Self-management Education and Support in Type 2 Diabetes A Joint Position Statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. The Diabetes Educator, 41(4), 417-430.
10. American Diabetes Association (2016). Standards of medical care in diabetes-2016 abridged for primary care providers. Clinical Diabetes. 33, 97–111. doi: 10.2337/dc12-s011

11. Brunisholz, K. D., Briot, P., Hamilton, S., Joy, E. A., Lomax, M., Barton, N., . . . Cannon, W. (2014). Diabetes self-management education improves quality of care and clinical outcomes determined by a diabetes bundle measure. Journal of multidisciplinary healthcare, 7, 533.
12. Chrvala, C. A., Sherr, D., & Lipman, R. D. (2015). Diabetes self-management education for adults with type 2 diabetes mellitus: A systematic review of the effect on glycemic control. Patient education and counseling.
13. Fan, L., & Sidani, S. (2009). Effectiveness of Diabetes Self-management Education Intervention Elements: A Meta-analysis. Canadian Journal of Diabetes, 33(1), 18-26. doi: http://dx.doi.org/10.1016/S1499-2671(09)31005-9
14. Newlin Lew, K., Nowlin, S., Chyun, D., & Melkus, G. (2014). State of the science: Diabetes self-management interventions led by nurse principal investigators. Western Journal Nursing Research, 36(9), 1111-1157.
15. Tang TS, Funnell MM, Oh M. Lasting effects of a 2-year diabetesself-management support intervention: outcomes at 1-year follow-up.Prev Chronic Dis. 2012;9:E109.
16. Kent, D., D'Eramo Melkus, G., Stuart, PM, McKoy, JM, Urbanski P, Boren SA, Coke L, Winters JE, Horsley NL, Sherr D, & Lipman R (2013). Reducing the risks of diabetes complications through diabetes self-management education and support.Popul Health Manag. 2013 Apr;16(2):74-81. doi: 10.1089/pop.2012.0020. Epub 2013 Feb 13
17. Reagan, L. , Walsh, S.J., Shelton, D. (2016) "Relationships of illness representation, diabetes knowledge, and self-care behaviour to glycemic control in incarcerated persons with diabetes", International Journal of Prisoner Health, Vol. 12 Iss: 3, pp.157 - 172 Int J Prison Health. 12;12(3):157-72. doi: 10.1108/IJPH-04-2015-0010.
18. Haney, C. (2001). From Prison To Home: The Effect Of Incarceration And Reentry On Children, Families, And Communities. The Psychological Impact of Incarceration: Implications for Post-Prison Adjustment. University of California, December, 2001, Santa Cruz, California.
19. Binswanger,I.A., Nowels, K., Corsi, K., Glanz, J., Long, J., Booth, R., & Steiner, J.F. (2012). Return to drug use and overdose after release from prison: a qualitative study of risk and protective factors. Addiction Science & Clinical Practice, 7, 3. doi:10.1186/1940-0640-7
20. Calcaterra, S., Beaty, B., Mueller, S., Min, S., & Binswanger, I. (2014). The association between social stressors and drug use/hazardous drinking among former prison inmates. Journal of Substance Abuse, 47, 41-49.
21. Cavanagh, J. F., Frank, M. J., & Allen, J. J. (2011). Social stress reactivity alters reward and punishment learning. Social cognitive and affective neuroscience, 6, 3: 311-320.
22. Thomas, E. H., Wang, E. A., Curry, L. A., & Chen, P. G. (2016). Patients' experiences managing cardiovascular disease and risk factors in prison. Health & justice, 4(1), 1.
23. Thomas, E. H., Wang, E. A., Curry, L. A., & Chen, P. G. (2016). Patients' experiences managing cardiovascular disease and risk factors in prison. Health & justice, 4(1), 1.
24. Fox, A. D., Anderson, M. R., Bartlett, G., Valverde, J., Starrels, J. L., & Cunningham, C. O. (2014). Health outcomes and retention in care following release from prison for patients of an urban post-incarceration transitions clinic. Journal of health care for the poor and underserved, 25(3), 1139.
25. Gallagher, C., LaFrance, B., & Neff, L., (March 2011). Group Medical Appointments Chronic Disease Care A Pilot Project. Paper at 4th Academic and Health Policy Conference on Correctional Health. Boston, MA. March 10-11, 2011.
26. Reagan, L. (2011, October). Inmates health beliefs about diabetes: Implications for diabetes education in the correctional setting. Proceedings of Custody and caring: 12th Biennial International Conference on the Nurse's Role in the Criminal Justice System (p. 42). Saskatoon, SK.
27. Wang, E. A., & Wildeman, C. (2011). Studying health disparities by including incarcerated and formerly incarcerated individuals. Jama, 305(16), 1708-1709.

28. Fisher, J.D., Fisher, W.A., Amico, K. R., & Harman, J.J. (2006). An information-motivation-behavioral skills model of adherence to antiretroviral therapy. Health Psychology, 25(4), 462-473.
29. Osborn, C. Y., & Egede, L. E. (2010). Validation of an information-motivation-behavioral skills model of diabetes self-care (IMB-DSC). Patient Education and Counseling, 79(1), 49–54.
30. de Vries, L., van der Heijden, A. A., van't Riet, E., Baan, C. A., Kostense, P. J., Rijken, M., ... & Nijpels, G. (2014). Peer support to decrease diabetes-related distress in patients with type 2 diabetes mellitus: design of a randomised controlled trial. BMC endocrine disorders, 14(1), 1.
31. Wolff, K., Chambers, L., Bumol, S., White, R. O., Gregory, B. P., Davis, D., & Rothman, R. L. (2016). The PRIDE (Partnership to Improve Diabetes Education) Toolkit Development and Evaluation of Novel Literacy and Culturally Sensitive Diabetes Education Materials. The Diabetes Educator, 42(1), 23-33
32. AADE. (2016). Diabetes Education Prompt Deck. Educator Guide.

Design, Procedures, Materials and Methods
Describe the study design, including the sequence and timing of all study procedures. Indicate expected start and completion dates. Include screening procedures, if any. The IRB strongly suggests that investigators incorporate flexibility into the study design to accommodate anticipated events (i.e. explain how missed study appointments can be made up by participants). If the research involves study of existing samples/records, describe how authorization to access samples/records will be obtained. If the study involves use of deception explain the reason why this is necessary. If applicable, describe the use of audiotape and/or videotape and provide justification for use. If this study offers **treatment** for the participants' condition, complete the **Treatment Study Supplemental Form** (IRB-1C) and attach it to this application for review. **If the study includes measures, survey instruments and questionnaires, i**dentify each and, if available, provide references for the measures. Describe what they intend to measure (relate to purpose/hypothesis) and their psychometric properties (e.g., reliability and validity). Identify any that were specifically created for the study.

Design: The proposed study will examine the feasibility, acceptability and preliminary efficacy measures of a quasi-experimental non-equivalent control group 6-week intervention study with repeated measures at baseline, 6 weeks, and 12 weeks. Acceptability of the DSS intervention will be examined using a qualitative descriptive design with focus group interviewing.

Prior to data collection, IRB approval from the University of Connecticut and the CDOC Research Advisory Council (RAC) will be obtained. Procedures for the recruitment of inmates with diabetes will be determined in collaboration with the Connecticut Department of Corrections administration (CDOC). Recruitment procedures as described in the prior section have been previously used and approved by the CDOC RAC. The final RAC approval has been obtained (see Connecticut department of Corrections letter of approval). . The RAC has reviewed this proposal and granted approval. After UCONN IRB and RAC approval, meetings with the Wardens will be arranged, email communication will be sent to Correctional Managed Healthcare (CMHC) nursing director (Attachment 2), recruitment flyers will be posted in the participating prisons, and the researcher will negotiate dates and times to be available during several Chronic Care Clinic sessions for in person recruitment as described in the recruitment procedures.

The "sick slips" from inmates requesting to hear more about the study will be collected from my assigned mailbox in medical records or another designated location and subsequently reviewed. Prior to scheduling a meeting with the potential participant, the PI will request that the DOC liaison or other designee review the list of potential participants to confirm that the participants meet the secure

classification to participate in groups. If interested potential participants do not meet the security classification, the PI will follow the DOC procedure for notifying participants who do not meet the DOC classification criteria.
All other interested potential participants will be contacted to meet with the PI. Similar to the system used for the PIs previous research, the researcher will work collaboratively with DOC liaison and the Correctional Officer (CO) routinely stationed in the medical clinic or infirmary of each prison site to schedule meetings with potential participants. The CO will call the cell block and ask that the inmate participant come to the medical clinic or another designated private room to meet with the PI.

The PI will negotiate dates and times to meet with interested inmates at a CDOC assigned private location- likely an exam or office space in the medical clinic. The door of the exam room will remain slightly ajar to provide privacy for inmate participant. The PI will sit in front of the inmate participant with her back to the slightly open door, this procedure was advised by the CDOC and used during prior interactions with inmate patients. The PI will be assigned a CDOC research liaison who will provide specifics of office or exam room location within the medical clinic. A corrections officer is stationed at some of the medical clinics or at a minimum makes rounds within the unit on a regular basis. Inmates will be screened using the screening script (Attachment 4) and if eligible, informed consent (Attachment 5) will be obtained. The inmate participant will be asked to read the Informed consent along with the researcher or if unable to read listen to the informed consent. Consent forms will be available in both English and Spanish if requested. Since patients will be able to speak and understand English, no interpreter is needed to assist with informed consent. They will be encouraged to ask questions and sign the form if they agree to participate.

If the inmate provides a negative response to any one question on the screening exam, he will be thanked for his time and transferred to the care of the CO for transport/disposition back to the living quarters.

After the potential participant consents to participate and signs the informed consent, the participant will be asked to complete the demographic survey (Attachment 7), the Health Literacy screening (Attachment 8) and the Montreal Cognitive Assessment, a measure of cognitive function (Attachment 9). If the participant is not able to recall his medications and if the participant has consented to allowing the PI to access the medical or pharmacy record, the PI will arrange to obtain a list of the participant's actual medications from the medical or pharmacy record. A HIPAA release form will be signed if needed after completion of demographic survey. Obtaining informed consent and baseline demographic and cognitive measures will be considered visit 1 for participants from the treatment and control facilities.

For the first two sessions (Group 1 First 48 participants) (Figure 1)The PI will screen potential participants until 48 participants are consented, and enrolled. Twenty-four participants in the designated Treatment facility (Cybulski Correctional Institution)divided into 2 groups of 12 will participate in the same DSS intervention on two separate occasions. Participants (n=24) in the Control facility (Osborn Correctional Institution) will receive the intervention upon completion of week twelve measurements. Figure 1 outlines the schedule for the informed consent, DSS intervention sessions, quantitative assessments and focus groups. As noted in the legend for figure 1. the Control group will receive the intervention after week 12 if they choose to do so.

The PI will begin screening, recruitment and informed consent procedures for Group 2 (the second set of 48 participants) when Group 1 (first 48 participants) completes Visit 4 (approximate start time) (Figure 1). Group 2 (n=24) in the control facility and n=24 in the treatment facility) will begin the DSS sessions and measurement schedule following the same procedures used for Group 1 and as described in Figure 1 Visits 2- 10. The support group is optional for those in the treatment facility because this aspect of the study is being evaluated after the DSS education sessions and three measurement intervals have been completed.

		Visit 1 Week 1 1.5 hours	Visit 2 Week 4 1.5 hours	Visit 3 Week 5 1 hour	Visit 4 Week 6 1 hour	Visit 5 Week 7 1 hour	Week 6 Week 8 1 hour	Visit 7 Week 9 1.5 hours	Visit 8 Week 11 2 Hours	Visit 9 Week 15 1 hour	Visit 10+ 1 hour/week Optional
			Measure 1					Measure 2		Measure 3	
Treat-ment Facility	Group 1 N=24 Group 2 (N=24) (n=12 per DSS session)	**Informed consent** STOFHLA MoCA Demographics	**Baseline Surveys** SKILLD[1] SCODI[2] OEQ[3] PAID[4] **Session 1 Topic** Diabetes Intro and Preparing for Discharge	**Session 2 Topic** Medicine taking	**Session 3 Topic** Monitoring	**Session 4 Topic** Hypo-glycemia	**Session 5 Topic** Basic Meal planning	**Surveys** SKILLD SCODI OEQ PAID **Session 6 Topic** Sick day manage post-release follow-up	Focus Group (2)	**Surveys** SKILLD SCODI OEQ PAID	Support Group
Control Facility[8]	Group 1 (N=24) Group 2 (N=24)	**Visit 1** **Week 1** **1.5. hours** **Informed consent** STOFHLA[5] MoCA[6] Demographic[7]	**Visit 2** **Week 4** **1 hour** **Measure 1** **Surveys** SKILLD SCODI OEQ PAID					**Visit 3** **Week 9** **1 hour** **Measure 2** **Surveys** SKILLD SCODI OEQ PAID		**Visit 4** **Week 15** **60 min** **Measure 3** **Surveys** SKILLD SCODI OEQ PAID	**Visit 5-10** **Week 15-20** **Optional** **DSS Sessions 1-6**

[1] Spoken Knowledge Low Literacy in Diabetes; [2] Self-care of Diabetes Inventory Confidence subscale; [3.] Diabetes Outcome Expectancies Questionnaire; [4]. Problem Areas in Diabetes, [5.] Short Test of Functional Health Literacy Adults, [6] Montreal Cognitive assessment, [7] Demographics [8] Control group to receive the intervention after week 12.

The exact timing of the support group in the treatment facility will be negotiated with the CDOC but will not start prior to the completion of 12-week data collection time point for group 1 and 2).

Intervention

The DSS sessions will be held in a room in the medical area away from other inmate activities. There will be a correctional officer (CO)present outside of the room at all times and the door of the conference room will be slightly ajar according to the DOC's safety related procedures. The first session of the six sessions will be 90 minutes' duration to allow for completion of the 4 instruments- the SKILLD (Attachment 10), SCODI (Attachment 11), and the PAID (Attachment 12,), OEQ (Attachment 13 note); The PI will read the instruments aloud to the group and collect the surveys before starting the session.

At the beginning of each group session, confidentiality guidelines and group expectations will be addressed and clearly stated by the student investigator at every group session. Group members will be told of the importance of maintaining confidentiality and that "what is shared in the group remains in the group" and any information shared in groups should not be discussed outside the group. This will be discussed with every group at the beginning of each session. Confidentiality guidelines will also be posted on a flip-board chart so it is visible for everyone to see and remember at every group session. Reminders not to discuss group topics outside the group will be reiterated at the end of the group session. These procedures will be maintained; however, confidentiality cannot be guaranteed

The PI will also remind the participants at the beginning of each session that she will be taking notes related to diabetes related questions or concerns.

Additionally, at the beginning of each group session members will be told what will happen if the student investigator is informed of self-harm intent and the obligation to refer the member to seek help from their healthcare provider. Since inclusion criteria selects only inmates who are preparing for release from prison this risk of self-harm is minimal but still needs to be identified and addressed.

The only limit to privacy is related to the lack of anonymity to the PI. However, as healthcare professionals the PI will be obligated to adhere to HIPAA guidelines and confidentiality guidelines of the group. The PI will adhere to the standard of confidentiality of group process and group sharing.

For session content, please refer to the intervention protocol (Attachment 15)

During the last thirty minutes of the 90 minutes scheduled for the last session, they will complete the 4 surveys. The PI will read all surveys aloud and collect the surveys after completion. All participants will be invited to participate in the audio recorded focus groups scheduled 2 weeks' post DSS sessions to evaluate acceptability of the DSS intervention. At the 6 week post DSS follow-up to complete questionnaires, the participants will receive a certificate of participation and be thanked for their time.

Focus Group Interviews

The FGIs will be scheduled approximately two weeks from the date of the sixth and final DSS session (Table III) They will be provided with the date negotiated with the CDOC prior to the last session and a reminder notice will be sent to all participants who reaffirm their consent to participate in the focus group.

The FGIs will consist of 8-10 participants, last approximately 90 minutes and be led by the PI. The PI will conduct at least one FGI in each facility for 8-10 participants. If more than 10 participants request participation, the PI will conduct additional FGIs. An interview guide (Attachment 14) will be used to

elicit information about the participant's acceptability of the DSS program. The focus will groups will be audio recorded and a CITI trained, approved CDOC nursing student will observe and take notes during all four of the focus group sessions.

The PI will review confidentiality guidelines and group expectations will be addressed and clearly stated at the beginning of the FGI. Group members will be told of the importance of maintaining confidentiality and that "what is shared in the group remains in the group" and any information shared in groups should not be discussed outside the group. This will be discussed with every group at the beginning of each session. Confidentiality guidelines will also be posted on a flip-board chart so it is visible for everyone to see and remember at every group session. Reminders not to discuss group topics outside the group will be reiterated at the end of the group session. These procedures will be maintained; however, confidentiality cannot be guaranteed. Participants can request that the audio recorder be turned off if they wish to make a statement when not being recoded. The PI will ask the participants if the PI may contact them to clarify any areas of the FGI. At the end of the FGI, the participants will be thanked for their time and escorted back to their cell. The focus groups will begin approximately two weeks from the date of the sixth and final DSS session (Table III Visit 8/week 11) for Group 1 and 2.

Table III. Focus Groups (8-10 participants per group) Intervention

Treatment Facility (2 hours)	Two Focus Group Sessions each for Group 1 and 2
Control Facility (2 hours)	Two Focus Group Sessions each for Group 1 and 2

Commented [LAR1]: Table revised

Support Group

For those participants in the DSS+ intervention in the treatment facility, they will have the option of participating in a weekly Diabetes support group to start after the 12-week data collection time point. The PI as facilitator of the support group adopts the support group facilitator strategies of connecting, exchanging information (e.g. correcting misinformation), managing group dynamics (coordinating flow and tone of support group discussion, facilitating peer to peer mentoring), and problem solving (e.g. skill reinforcement and practice) (Costello, 2013). There will not be any specific topics will be planned. The participants will interact with each other about matters relative to diabetes and preparing for release. The PI will observe and take notes during the support group. The support sessions will be 60 minutes' duration and will occur weekly or biweekly if interest is lacking e.g. no participation. The exact timing of the support will be negotiated with the CDOC but will not start prior to the 3 month post-DSS session data collection).

Costello, J. F. (2013). Roles and Strategies of Diabetes Support Group Facilitators An Exploratory Study. The Diabetes Educator, 0145721713476347.

Data Analysis:

Measures:

1. Demographic survey (Attachment 7). Sociodemographic variables include age, gender, ethnicity, health status (type of diabetes, duration of illness and/or age at diagnosis), medications including dose, type, frequency, and administration method (keep on person[KOP], or direct observation medication line), medical problems, mental illness and prior alcohol/substance abuse, and years in prison.

2. Functional **Health literacy** will be measured by the S-TOFHLA (Attachment 8).[1] The S-TOFHLA has been widely used with reported Cronbach's alpha at 0.97.27 It has been widely used with diverse populations.

3. **Cognitive function** will be measured by the Montreal Cognitive Assessment (MoCA)[2](Attachment 9) is designed as a rapid screening instrument for mild cognitive dysfunction. It assesses different cognitive domains: attention and concentration, executive functions, memory, language, visuoconstructional skills, conceptual thinking, calculations, and orientation and takes approximately 10 minutes to administer. The total possible score is 30 points; a score of 26 or above is considered normal. Internal consistency of the MoCA ranges from 0.72 – 0.83. Cronbach's alpha in geriatric, mixed clinical population and stroke and vascular dementia populations.

4. Feasibility measures Aim1: Feasibility will be will be evaluated with recruitment and enrollment tracking forms, attendance sheets, field notes, adherence to intervention manual, participant workbook entries, glucose meter procedure manual, and blood glucose logs to obtain data needed to support hypotheses. Reliability of all instruments will be evaluated.

5. Acceptability measure Aim 2: Data will be obtained using an IRB approved FGI guide e.g. probes such as perspective about the overall quality of the program? Or how well did the program prepare you for transitioning to the community?**Preliminary Efficacy measure: Dependent Variables:**

1.**Diabetes knowledge** diabetes knowledge. Spoken Knowledge in Low Literacy for Diabetes scale (SKILLD) (Rothman et al., 2005)[3](Attachment 10) is a 10-item scale that measures diabetes knowledge and takes less than 10 minutes to administer. Each item is scored as correct (0) or incorrect (1). Total scores range from 0-100 % with higher scores indicating greater diabetes knowledge. Coefficients of internal reliability for the SKILLD have been reported at 0.72 (Kuder Richardson Coefficient of reliability) (Rothman et al., 2005) and 0.54 (Cronbach's alpha) (Jeppesen, Hull, Raines, & Miser, 2012).[4] Both Rothman et al.'s (2005) and Jeppesen et al.'s [4] (2012) studies supported construct validity and moderate criterion validity with the SKILLD. Additionally, as was done for the current study, individual items can be analyzed as the percentage of participants' who responded correctly. The SKILLD instrument when used to evaluate knowledge in a population of incarcerated person with diabetes had Cronbach's alpha of 0.65 [5] (H12-303). Both health literacy ($p>0.05$) and perceived knowledge about diabetes ($p<0.05$) were associated with diabetes knowledge and that the direction of the association was positive.

2. **Self-efficacy** will be measured with the 11 item Self-care of Diabetes Inventory (SCODI) Confidence Subscale[6] (Attachment 11). The SCODI measures the degree of confidence the person has about his or her ability to perform specific self-care task and to persist in forming an action despite barriers. The SCODI is scored on a standardized scale of 0-100 with higher scores indicating higher confidence. The SCODI has a global reliability index for multi-dimensional scales of 0.89 and alpha reliability of 0.80. The length of time to administer is not documented in the literature.

3. **Diabetes Related Emotional Distress** will be measured with the PAID (Problem Areas in Diabetes) scale (Attachment 12). The PAID consists of 20 items with each item scored 0 to 4 ("Not a problem" to "Serious Problem"). The sum of the 20 items is multiplied by 1.25 to yield a final score 0-100 with higher scores indicating greater distress. Internal consistency has been reported at 0.90 and has been consistently high [,,7,8].

4. **Outcome Expectancies Questionnaire (OEQ)** (Attachment 13), a 20 item instrument, will measure Outcome expectancies or a "person's perceptions of the consequences of performing diabetes self-care behavior". [9] Perceptions of the consequences of an outcome have been associate linked to motivation to perform a behavior. A high score on the OEQ indicates suggest strong beliefs that the performance of specific diabetes behaviors will lead to a specific outcome. [10] The OEQ Cronbach's alpha has been reported at 0.80.

1. Baker DW, Williams MV, Parker RM, Gazmararian JA, Nurss J. Development of a brief test to measure functional health literacy. Patient Education and Counseling. 1999;38:33–42
2. Nasreddine, Z. S., Phillips, N. A., Bédirian, V., Charbonneau, S., Whitehead, V., Collin, I., ... & Chertkow, H. (2005). The Montreal Cognitive Assessment, MoCA: a brief screening tool for mild cognitive impairment. Journal of the American Geriatrics Society, 53(4), 695-699.
3. Rothman, R. , Malone, R., Bryant,B., Wolfe, C., Padgett, P.,DeWalt, D., Weinberger, M.Pignone,M.(2005). The Spoken Knowledge in Low Literacy in Diabetes Scale. The Diabetes Educator, 31(2), 215-224.
4. Jeppesen, K., Hull, B., Raines, M., and Miser, F. (2012). A Validation Study of the Spoken Knowledge in Low Literacy in Diabetes Scale (SKILLD). Journal of General Internal Medicine, 27 (2), 207-212.
5. Reagan, L. , Walsh, S.J., Shelton, D. (2016) "Relationships of illness representation, diabetes knowledge, and self-care behaviour to glycemic control in incarcerated persons with diabetes", International Journal of Prisoner Health, Vol. 12 Iss: 3, pp.157 - 172 Int J Prison Health. 12;12(3):157-72. doi: 10.1108/IJPH-04-2015-0010
6. In review, pending reference from author.
7. Polonsky WH, Anderson BJ, Lohrer PA, Welch G, Jacobson AM, Aponte JE, Schwartz CE (1995). Assessment of diabetes-related distress. Diabetes Care 1995;18:754-60.
8. Welch GW, Jacobson AM, Polonsky WH (1997). The Problem Areas in Diabetes Scale: An evaluation of its clinical utility. Diabetes Care 20:760-766, 1997.
9. Glasgow, R. E., Toobert, D. J., Riddle, M., Donnelly, J., Mitchell, D. L., & Calder, D. (1989). Diabetes-specific social learning variables and self-care behaviors among persons with type II diabetes. Health Psychology, 8(3), 285.
10. Chlebowy, D. O., & Garvin, B. J. (2006). Social support, self-efficacy, and outcome expectations impact on self-care behaviors and glycemic control in Caucasian and African American adults with type 2 diabetes. The Diabetes Educator, 32(5), 777-786

Justification of Sample Size: For qualitative and pilot studies, describe how the proposed sample size is appropriate for achieving the anticipated results. For quantitative studies, provide a power analysis that includes effect size, power and level of significance with references for how the sample size was determined. Explain the rate of attrition, with references as appropriate. Data Analysis: For all studies, provide a description of the statistical or qualitative methods used to analyze the data.

Quantitative:

Demographic data, sociocultural and cognitive function will be analyzed with univariate statistics.

Justification of Sample size: h.

Previous research 24 has demonstrated that, in diabetes behavioral interventions targeting the variable “diabetes knowledge,” an effect size of 0.47-0.68 is achievable at $p < .05$. Therefore, with a moderate effect size (d=0.50), $p<0.05$, power 0.80, 2 groups, and an estimated moderate correlation (0.50) between 3 repeated measures, the power analysis 25 indicated a need for 86 participants.

Attrition for DSME programs is reported to range as high as 20- 50%. 2,3. This wide variation and high rate of attrition has been reported as being multifactorial e.g. group versus individual program, accessibility, timing, presence of depression, older age of participant.4,5 Attrition rates for group DSME has been lower than non-group education.5 There is no data on attrition rates for DSME or other similar programs in the prison. Factors possibly influencing attrition in the prison that need to be considered include movement of incarcerated persons between facilities and other restrictions of movement e.g. lockdown. 6 During the PI’s previous research, communication with the facility and CDOC designee was critical to identify real or potential issues affecting data collection. The PI will employ the following strategies to reduce attrition:

1. Confirm with the CDOC designee prior to participant enrollment that the potential participant is within 6-9 months of release to the community. 2. Schedule the DSS+ sessions during the evening and possibly on the weekend to avoid conflicts with the participants work or day schedule. This strategy recommended by the CDOC administration and employed during the PI’s prior research worked well when scheduling meetings with potential participants. Attendance for Potential participants who signed up to meet with the PI on a specific date to hear more about the study and possibly participate in the study was high. Only 2 potential participants declined to come for the scheduled meeting due to attendance at a religious service. 3. The CDOC designee will send reminders to DSS session participants the day before the scheduled session.

2.

For these reasons, the PI expects attrition to be low for this study 5-10% and supports the sample size of 96. It is estimated that the PI will screen 100-150 potential participants to achieve a total sample of 96 to account for attrition as high as 10%.Furthermore, one of the purposes of this feasibility study is to evaluate attrition.

1. Leon, A.C., Davis, L.L., & Kraemer, H.C. (2011). The role and interpretation of pilot studies in clinical research. Journal of Psychiatric Research, 45 (5), 626-629.

2. , S. L., Lau, J., Smith, S. J., Schmid, C. H., & Engelgau, M. M. (2002). Self-Management education for adults with type 2 Diabetes A meta-analysis of the effect on glycemic control. Diabetes care, 25(7), 1159-1171.

3. Sarkisian, C. A., Brown, A. F., Norris, K. C., Wintz, R. L., & Managione, C. M. (2003). A systematic review of diabetes self-care interventions for older, African American, or Latino adults. The Diabetes Educator, 29(3), 467-479.

4. Adams, K. F., Sperl-Hillen, J. M., Davis, H., Spain, C. V., Hanson, A. M., Fernandes, O. D., ... & Beaton, S. (2013). Factors influencing patient completion of diabetes self-management education. Diabetes Spectrum, 26(1), 40-45.

5. Gucciardi, E., DeMelo, M., Offenheim, A., Grace, S. L., & Stewart, D. E. (2007). Patient factors associated with attrition from a self-management education programme. Journal of evaluation in clinical practice, 13(6), 913-919.

6. Reagan, L., & Shelton, D. (2016). Methodological factors conducting research with incarcerated persons with diabetes. Applied Nursing Research, 29, 163-167.

Statistical strategy:

Data will be analyzed using SPSS. Descriptive methods will be used to generate summary statistics of demographic and study variables to answer questions 5 about feasibility. We will use the information obtained under Aim 1-3 to further refine the intervention.

Aim 1 Feasibility: Counts, percentiles, measures of central tendency, and correlations will be examined to provide information to address each hypothesis in Aim 1. Additionally, quantitative content analysis using apriori themes from Diabetes Education Prompt Deck 34 from the PIs experience conducting research with incarcerated persons will be used to further assess participant engagement(H3) and intervention implementation(H5).

Aim 2 Acceptability, Qualitative data from each FGI transcript (unit of analysis) will be analyzed with Krippendorff 43method of qualitative content analysis. An iterative process of coding and categorizing the data will be used to identify themes within and across transcripts. Two researchers will read each transcript, several times to come to consensus on themes.

Aim 3 Preliminary efficacy of the effect of the DSS training on the IMB outcome variables will be evaluated with repeated-measures ANOVA and for the assumptions of repeated measures ANOVA.
Qualitative

The Focus Group Interview (FGI) will be guided by the interview guide (Appendix). Focus Groups Interview (FGIs) will be audiotaped with verbatim transcriptions, entered into a password secured Word file and imported into ATLAS/TI software for data management. Qualitative data from each transcript will be analyzed with Krippendorff method of qualitative content analysis. An iterative process of coding and categorizing the data will be used to identify themes within and across transcripts. Two researchers will review each transcript, read each transcript several times to come to consensus on themes.

Justification of Sample size: The rule of thumb is to conduct 4 focus groups and then determine if saturation is reached [7] Consensus is lacking in the literature on the total number of participants needed to achieve data saturation but five to eight participants but not more than 10 is usually adequate for most noncommercial topics when using focus group interviewing techniques. [7] The PI will enroll 10 participants per group to account for no-shows.

7. Kreuger, K.A. & Casey, M.A. (2009). *Focus Groups a Practical Guide for Applied Research*. 4th ed.Washington DC.

Inclusion/Exclusion Criteria
List major inclusion and exclusion criteria. Any proposed exclusion criterion based on gender (women of childbearing potential), age, or race must include justification for the exclusion. Describe the conditions under which participants may be removed from the study, i.e., noncompliance with study rules, study termination, etc.

1. Inclusion Criteria:
All persons with Type 1 or 2 diabetes of male gender, any race or ethnicity who are incarcerated in selected Connecticut prisons as negotiated with CDOC (Osborn Correctional Institution, Somers, CT, and Cybulski Correctional Institution, Somers, CT) will be eligible to participate if he:

- Has Type 1 or 2 diabetes
- Is within 6-9 months of release from prison
- Is able to speak and understand English
- Is age 18 or over.
- Agrees to voluntarily participate
- Has capacity to provide written consent.

2. Exclusion criteria

- inmate patients who do not have diabetes
- Inmates who do not speak and understand English.
- Inmates who are in segregation or otherwise ineligible due to safety and security policies.

3. Justification for exclusion: There is no one on the study team fluent in Spanish. This study has limitedfunding.

4. Conditions under which inmates may be removed from the study: Those who are unable to provide consent and/or are in administrative segregation, the hospital, or demonstrate any illegal behavior or are removed by their primary clinician or the CT DOC for safety reasons. The subject of disclosure of any illegal activity will be outlined in the consent sheet noting that the facilitators are mandated to report if a participant is disclosing that they are thinking of hurting themselves, others or breaking the law. All participants are informed of this verbally at time of consent. The PI's past experience with inmate populations has provided her with the experience that inmate participants are well aware of these facts.

Risks and Inconveniences
Describe the potential risks to participants (and secondary participants, if applicable) and *steps taken to minimize risks*. Assess the likelihood of the risk occurring and, if it were to occur, the seriousness to the participant. Types of risks to consider include: physical, psychological, social, legal, employment, and financial. Also describe any anticipated inconveniences the participants may experience (time, abstention from food, etc.).

Physical Risks:	Procedures to Protect Against / Minimize Risks	Likelihood of Occurrence	Seriousness too Subject if Risk Occurs
Participant who uses insulin or anti-hyperglycemic medications e.g. insulin may experience symptomatic hypoglycemia if consent, didactic or focus group sessions, disrupts meal or snack schedule.	The Researcher will: 1. coordinate with the CTDOC to schedule all sessions (consent meeting, didactic DSS and focus group) at a time to not interfere with meal and insulin administration. 2. confirm with the potential or actual participant who presents for a consent meeting or didactic or focus group session that timing of meals and medication/insulin administration were not being interpreted by the 3. monitor participant for signs and symptoms of hypo/hyperglycemia during all sessions and seek help from nursing staff if needed.	Minimal	Moderate
There is a potential for violence to break out during the focus or support group.	The researcher will:1. Coordinate with CTDOC administration during all phase of the research but specifically for formation of the DSS education sessions, support and focus groups. Ongoing communication will occur between the CDOC staff designated to approve inmates for participation in support groups.	Minimal	Serious

Psychological Risks:	Procedures to Protect Against / Minimize Risks	Likelihood of Occurrence	Seriousness to Subject if Risk Occurs

Participants may feel Inconvenienced with the time it takes to participant in didactic, support and focus group sessions.	Efforts will be made to align procedures with inmate's treatment as usual (TAU) schedules, and appointments are made with inmates when our activities infringe upon their free time so that they have the option of participating at a time that is convenient for them.	Moderate	Minimal
Participants in the DSS treatment or Control group may be transferred to another correctional facility or released from prison before the end of the DSS program. As a result of these unplanned events, the participant may feel disappointed about not being able to complete the program.	The DOC will communicate with the PI about impending transfers or early release dates. For transfers, the DOC will ask the participant if he would prefer to delay transfer until the end of the DSS. If not, the PI will meet with the participant prior to or after transfer to provide all of the education materials and answer any questions. If the participant is to be released from prison earlier than anticipated, the PI will meet with participant prior to discharge to provide all of the education materials associated with the 6-DSS sessions and answer their DSS related questions.	Moderate	Minimal
Although incarcerated persons are used to being on waitlists for CDOC programming or other usual care services, potential or enrolled participants in the control group may be frustrated with waiting12 weeks for the DSS intervention.	Potential participants who will be assigned to the control group may decline participation in the study if they do not want to wait for participation. Enrolled participants may withdraw from the study at any time and will be told this during informed consent.	Minimal	Minimal

Economical Risks:	Procedures to Protect Against / Minimize Risks	Likelihood of Occurrence	Seriousness to Subject if Risk Occurs
None	NA	NA	NA

Social Risks:	Procedures to Protect Against / Minimize Risks	Likelihood of Occurrence	Seriousness to Subject if Risk Occurs
Inmates may feel uncomfortable if others in the facility know they are participating in a research study.	All measures will be taken to ensure a participant's privacy and no information will be disclosed to any third parties without the participant's permission. All research personnel are certified in meeting HIPAA requirements.	Minimal	Minimal to Moderate
The focus group session will be audio-recorded in order to accurately capture what is said. Although the researchers will take every precaution to maintain confidentiality of the data, the nature of focus and support groups prevents the researchers from guaranteeing confidentiality.	Participants: 1. may request that the recording be paused at any time. 2. can choose how much or how little you want to speak during the group. 3. may request to leave the focus group at which time, a CO will be notified, and upon approval by the CO, the participant will return to his cell. 3. will be asked not to use any names during the focus and support group discussion. 4. will be asked to verbally commit to maintaining	Moderate	Moderate

Legal Risks:	Procedures to Protect Against / Minimize Risks	Likelihood of Occurrence	Seriousness to Subject if Risk Occurs
Request of research records by court subpoena	The PI is not collecting any information related to participants'' criminogenic activity or nature of their conviction or criminal offense.	Minimal	Minimal

Benefits
Describe anticipated benefits to the individual participants. If individual participants may not benefit directly, state so here. Describe anticipated benefits to society (i.e., added knowledge to the field of study) or a specific class of individuals (i.e., athletes or autistic children). Do not include compensation or earned course credits in this section.

Individual participant benefits: Benefits of participation in this study greatly outweigh the risks involved to participants. As a result of participating in the DSS+ program, incarcerated person with diabetes could gain knowledge, be more confident in their ability to self-manage and be better prepared to self-manage diabetes upon release to the community.

As an indirect benefit of participation: Inmates who participate in this study could potentially stimulate improvements to existing diabetes programming and as a result feel good about their participation.

Anticipated benefits to society: Findings from this research will inform Diabetes Group education for incarcerated persons TTC. Evidence produced from this research will begin to reduce the disparity for the availability of evidence base care between persons with diabetes living in prison and those living in the general population.

Risk/Benefit Analysis

Describe the ratio of risks to benefits. Risks to research participants should be justified by the anticipated benefits to the participants or society. Provide your assessment of anticipated risks to participants and steps taken to minimize these risks, balanced against anticipated benefits to the individual or to society.

We expect that there is low risk vs high benefit to the participant. Again, benefits of participation in this study greatly outweigh the risks involved to participants. Risks as addressed above have been assessed as a minimal to moderate level with the exception of the court requested subpoena of study transcripts. The researcher will follow the above stated procedure (refer to table under risk/inconvenience) to minimize all risk. All measures will be taken to ensure a participant's privacy and no information will be disclosed to any third parties without the participant's permission. All research personnel are certified in meeting HIPAA requirements.

Economic Considerations
Describe any costs to the participants or amount and method of compensation that will be given to them. Describe how you arrived at the amount and the plan for compensation; if it will be prorated,

please provide the breakdown. Experimental or extra course credit should be considered an economic consideration and included in this section. Indicate when participants will receive compensation.

. All participants will be provided with a glucose meter free of charge (approximate value $30.00) when they leave the prison.

Data Safety Monitoring
This is a prospective plan set up by the study investigators to assure that adverse events occurring during studies are identified, evaluated, and communicated to the IRB in a timely manner. Although the investigators initially propose a Data Safety Monitoring Plan (DSMP), the IRB must approve the plan and may require revision of the plan. A DSMP is required for all human studies at the University of Connecticut except for studies determined to be exempt from continuing IRB review. For studies that present more than minimal risk to participants, the IRB will review and determine on a case-by-case basis whether a data safety monitoring board is most appropriate. Please refer to the IRB's policy regarding data safety monitoring *before* completing this section - http://irb.uconn.edu/irb_sop/IRBSOP_submission.html#data_safety_monit.

Issues that should be addressed in the DSMP include the following:
1) frequency of the monitoring
2) who will conduct the monitoring (Under UConn policy a student cannot be the sole person responsible for monitoring the data and safety of the protocol procedures.)
3) what data will be monitored
4) how the data will be evaluated for problems?
5) what actions will be taken upon the occurrence of specific events or end points
6) who will communicate to the IRB and how communication will occur

Sample response to issues listed above for minimal risk/slight increase over minimal risk – "Survey results will be monitored by the PI in conjunction with the student investigator once every two weeks (items 1, 2 and 3). Survey responses will be reviewed to monitor for clarity (i.e., the same question is skipped by 5 or more participants). In that case, the question will be revised and an amendment will be submitted to the IRB (items 4, 5 and 6)."

The PI, Louise Reagan PhD, will oversee the study procedures for data acquisition and validation. Survey results will be monitored by Louise Reagan once a month until completion of the study. Survey responses and audio transcripts will be reviewed to monitor for clarity. If a problem is noted with data clarity, the question will be revised and an amendment will be submitted to the IRB. Data safety is assured through: 1) a common core of conjoint training and routinely scheduled fidelity monitoring; 2) continuous team (agency & faculty) feedback through weekly and monthly meetings with telephone and email communication as needed; and 3) final data editing and entry at UCONN School of Nursing; Any paper forms are retained in a locked file in at UConn Center for Nursing Scholarship locked file with access provided only to those who are involved in the project. Computer files are password protected on faculty computers. Access provided only to those working on the project. Any variation from protocol will be corrected within two days and reported to the IRB within the same week.

Privacy/Confidentiality
Explain how the privacy interests of participants will be maintained during the study (note that privacy pertains to the individual not to the data). Describe procedures for protecting confidentiality of data collected during the study and stored after study closure. Describe how data will be coded. Describe plans for storage and security of electronic data (plan must comply with the University's Policy on the

Security Requirements for Protecting University Data at Rest). If identifiable, sensitive information (illegal drug us
e, criminal activity, etc.) will be collected, state whether a Certificate of Confidentiality will be obtained. Be sure to state whether any limits to confidentiality exist and identify any external agencies (study sponsor, FDA, etc.) that will have access to the data. If participants will be screened, describe the plans for storage or destruction of identifiable data for those that failed the screening.

Only the principal investigator (Louise Reagan) and UCONN IRB and CTDOC RAC approved members of the research team will have access to the information obtained on all the questionnaires.

The following procedures will be used to protect the confidentiality of the participants' data. The researchers will keep all study records locked in a secure location. Research records will be labeled with a code. The code will be derived from a number (1-125). A master key that links names and codes will be maintained in a separate and secure location at the UCONN school of Nursing. The master key will be destroyed after 3 years. All electronic files (e.g., database, spreadsheet, etc.) containing identifiable information will be password protected. Any computer hosting such files will also have password protection to prevent access by unauthorized users. Only the members of the research staff will have access to the passwords. Data that will be shared with others will be coded as described above to help protect the participant's identity. Data will be disseminated in as de-identified data in all publications and presentations. Records will be maintained for three years per the IRB policy.

Limits to protecting the participants' confidentiality exist if an inmate discloses child abuse and neglect, or harm to self or others. If an insurer, medical care provider, or another person obtains

The participant's written consent to receive research information, then the researchers will not withhold the requested information.

SECTION VIII: Informed Consent

As PI, you are responsible for taking reasonable steps to assure that the participants in this study are fully informed about and understand the study. Even if you are not targeting participants from "Special Populations" as listed on page 4, such populations may be included in recruitment efforts. Please keep this in mind as you design the Consent Process and provide the information requested in this section.

Consent Setting

Describe the consent process including *who* will obtain consent, *where* and *when* will it be obtained, and *how* much time participants will have to make a decision. Describe how the privacy of the participants will be maintained throughout the consent process. State whether an assessment of consent materials will be conducted to assure that participants understand the information (may be warranted in studies with complicated study procedures, those that require extensive time commitments or those that expose participants to greater than minimal risk).

The PI will obtain informed consent from all participants. For those participants who speak and understand English but prefer to read Spanish (determined by self-report), the PI will provide a copy of the consent form in Spanish and have the potential participant read the consent while the researcher reads the English version of the informed consent out loud to the participant. The informed consent process will be conducted in a room designated by the CDOC administration. Once IRB approval is obtained, the PI will meet with the CDOC Research Advisory Council (RAC). At this time a CDOC research liaison who will assist with these details will be assigned to the PI. Considering that the PI will be interviewing inmates in two facilities, a location for the interview will be dependent on both the safety and security requirements of the facility and the privacy of the inmate participant.
Modification of consent procedure for group 1(n=48)

Capacity to Consent
Describe how the capacity to consent will be assessed for participants with limited decision-making capacity, language barriers or hearing difficulty. If a participant is incapable of providing consent, you will need to obtain consent from the participant's legal guardian (please see the IRB website for additional information).

Low reading capabilities are expected. The inmate will be provided a copy of the English or Spanish version of the consent form as it is read to them. Inmates will have the opportunity to ask questions. They will be told that they have time to make their decision. They will be asked to verbally report back their understanding of the consent form (Teach Back method). The PI has 16+years' experience as a Primary Care Provider and working on a Mobile Medical Van communicating with patients who have Limited English proficiency and low literacy and health literacy. Using Teach back technique (Schillinger et al., 2003) while watching facial expression will be employed to assess capacity to consent. Their ability to articulate a primary understanding regarding the consent will be accepted as their ability to provide consent. They are allowed the opportunity to withdraw at any time without penalty.

Parent/Guardian Permission and Assent
If enrolling children, state how many parents/guardians will provide permission, whether the child's assent will be obtained and if assent will be written or oral. Provide a copy of the script to be used if oral assent will be obtained.

NA

Documentation of Consent
Specify the forms that will be used for each participant population, i.e., adult consent form, surrogate consent form, child assent form (written form or oral script) or an information sheet. Copies of all forms should be attached to this application in the same format that they will be given to participants (templates and instructions are available on the IRB website).

Adult Consent Form

Waiver or Alteration of Consent
The IRB may waive or alter the elements of consent in some minimal risks studies. If you plan to request either a **waiver of consent** (i.e., participants will not be asked to give consent), an **alteration of consent** (e.g., deception) or a **waiver of**

signed consent (i.e., participants will give consent after reading an information sheet), please answer the following questions using specific information from the study:

Waiver (i.e. participants will not be asked to give consent) or alteration of consent (e.g. use of deception in research):

- Why is the study considered to be minimal risk?

NA

- How will the waiver affect the participants' rights and welfare? The IRB must find that participants' rights are not adversely affected. For example, participants may choose not to answer any questions they do not want to answer and they may stop their participation in the research at any time.

NA

- Why would the research be impracticable without the waiver? For studies that involve deception, explain how the research could not be done if participants know the full purpose of the study.

NA

- How will important information be returned to the participants, if appropriate? For studies that involve deception, indicate that participants will be debriefed and that the researchers will be available in case participants have questions.

NA

Waiver of signed consent (i.e. participants give consent only after reading an information sheet):

- Why is the study considered to be minimal risk?

Prior to scheduling a meeting with the potential participant, the PI will request that the DOC designee (Jennifer Benjamin RN, MSN, DNP, Correctional Health Services Program Director), review the sick slip requests of persons interested in participating to confirm that the inmate can be released form their units. Some inmates (potential participants) who have a higher DOC assigned security classification are not allowed to participate in groups. If interested potential participants do not meet the security classification, the PI will follow the DOC procedure for notifying participants who do not meet the DOC classification criteria. Confirming security classification is a routine procedure in the prison performed prior to all inmate activities and does not confer additional risk to the potential participants.
After this procedure, The PI will proceed with contacting the inmate, scheduling an appointment to meet, follow the procedures described in the screening for eligibility (Attachment 4), obtain informed consent and begin study procedures. No study procedures will occur until after participant signs the consent.

- Does a breach of confidentiality constitute the principal risk to participants? Relate this to the risks associated with a breach of confidentiality and indicate how risks will be minimized because of the waiver of signed consent.

The PI will collect no personally identifiable information during the screening for eligibility process. As stated above, it is standard procedure to review the CT DOC security classification prior to all inmate group activities.

- Would the signed consent form be the only record linking the participant to the research? Relate this to the procedures to protect privacy/confidentiality.

No~~Yes~~. Research records will be labeled with a code. The code will be derived from a number (1-125). A master key that links names and codes will be maintained in a separate and secure location at the UCONN school of Nursing.

- Does the research include any activities that would require signed consent in a non-research setting? For example, in non-research settings, normally there is no requirement for written consent for completion of questionnaires.

NO

HIPAA Authorization

On the Storrs campus, the following sites are covered entities under the Health Insurance Portability and Accountability Act:

1. Nayden Rehabilitation Clinic (outpatient physical therapy)
2. Speech and Hearing Clinic
3. Emergency Medical Services (EMS, Ambulance)

If research participants are recruited through these entities, it may be necessary to obtain a Waiver of Authorization to allow you to access records for recruitment and an Authorization to use and disclose Protected Health Information (PHI). Contact the Office of Research Compliance at 860-486-8802 for additional information. **Note:** Student Health Services is not covered by HIPAA; however, FERPA regulations apply.

Principal Investigator Certification

I understand the University of Connecticut's policies concerning research involving human participants and I agree:

1. To comply with all IRB policies, decisions, conditions, and requirements;
2. That this study has been designed, to the best of my knowledge, to protect human participants engaged in research in accordance with the standards set by the University of Connecticut, the United States Department of Health and Human Services, the Food and Drug Administration, and any other sponsoring agency;
3. To obtain prior approval from the IRB before amending the research protocol or the approved consent/assent form;
4. To report to the IRB in accordance with IRB policy, any adverse event(s) and/or unanticipated problem(s) involving risks to participants;
5. To submit the Re-Approval/Completion Form as needed;
6. That my participation and the participation of any co-investigators does/do not violate the University of Connecticut policy on Individual Conflicts of Interest in Research;
7. That each individual listed as study personnel in this application has a) completed the required human subjects training, and b) are knowledgeable of the study procedures described in the protocol;
8. That each individual listed as study personnel in this application possesses the necessary training and experience for conducting research activities in the role described for them in this research study.

Furthermore, by signing below, I also attest that I have appropriate facilities and resources for conducting the study.

Original Signature of Principal Investigator	**Date**

Original Signature of Student Investigator (Only for Student-Initiated Research)	**Date**

Original Signature of Medical Monitor (Required for all studies that will be monitored by a Physician)	**Date**

Department Head Certification

This is to certify that I have read the protocol and believe that there is value in asking and answering these research questions using the approach described in this application. To the best of my knowledge, the researcher(s) have the time, facilities, and expertise to conduct this study.

Original Signature of Department Head (Required for ALL studies, unless grant application/contract is attached; see Section III)	**Date**

Consent Form for Participation in a Research Study

Principal Investigator: Louise Reagan, PhD
Study Title: A Study to Evaluate the Feasibility and Acceptability of a Diabetes Survival Skills + (DSS+) Intervention for Incarcerated Persons Transitioning to the Community (TTC):

Introduction

I am faculty member in the School of Nursing at the University of Connecticut.

You are asked to help us determine if a diabetes education program and support group called Diabetes Survival Skills+ (DSS+) is acceptable to incarcerated person preparing for release from prison. The diabetes survival skills education is a six session program designed to provide you with the basic survival skills such as understanding the basic facts about diabetes, and taking diabetes medications or insulin, testing and keeping track of your blood sugar, recognizing and treating low blood sugar or hypoglycemia, and how to eat healthy and make an appointment with a doctor or nurse practitioner who will help you care for diabetes upon release from prison. We are also interested in learning if this diabetes education program has an effect on what you know and believe about diabetes, your confidence level in taking care of your diabetes, and your stress associated with diabetes. After the 6 diabetes education sessions, you can participate in a weekly or bi-weekly diabetes support group until the time of your release from prison.

A grant from the University of Connecticut's Office of the Vice President for Research (OVPR)will provide some funding for this study. The funding will be used to pay for a nursing student to assist me with the study, education materials, and a statistician to help with analyzing the information obtained from questionnaires completed by the participants.

You are being asked to participate because you have diabetes and you will be released from prison within the next 6-9 months.

- You do not have to be in the study.
- If you say yes, you can quit at any time.
- Please take as much time as you need to make your decision.
- Your medical care will not change in any way if you say no.

Why is this study being done?

We want to learn more about what type of education program helps incarcerated persons to be prepared for managing diabetes when no longer incarcerated.

We will use this information to plan diabetes education for incarcerated persons with diabetes leaving prison to help prepare them to care for diabetes while living in the community.

What will I be asked to do?

If you agree to be in the study, we will meet at least 9 times or more if you decide to participate in the support group.

Visit 1: we will meet for 90 minutes or less at the correctional facility where you live. After you agree to be in the study and sign this document, you will be asked to complete 3 forms. I will read questions aloud asking you:

- your age, highest grade completed in school, gender, date of release from prison, how long you were in prison, type of diabetes, medical history and medications, whether you have use or have used alcohol or drugs, and if or when you have participated in a diabetes education class.
- to read information about health and answer a few questions about what you read.
- to draw objects, and recall name of objects that are shown to you.
- You do not have to answer any questions that you do not want to answer. There are no right or wrong answers to these questions.
- If you cannot name all of your medications and medical conditions, I will ask you to sign a permission slip (HIPAA release) allowing me to look at your medical and pharmacy record to obtain a list of your medications and medical conditions (illnesses). You can refuse this request. Because we need an accurate list of your medications and medical conditions, you will not be able to participate in the study if you prefer that we not look at your

medical record.

- After you have completed all 3 forms, the Officer will escort you to your living area. Once we are ready to start the group diabetes education program within the next month, I will send you a reminder stating the date of the first Diabetes Education session.

Visit 2: Within the next month, we will meet for 90 minutes in a room at the correctional facility with 10-12 other incarcerated persons with diabetes who are also participating in the study. You will be asked to complete 4 questionnaires. I will read the surveys aloud to you and the other participants. You will be asked questions about:

- what you know about diabetes.
- how confident you feel about caring for your diabetes.
- your beliefs and feelings about diabetes
- the level of concern or stress you feel about diabetes and diabetes self-care tasks.

After you complete the surveys that will take approximately 30 minutes, you will participate in a diabetes education class for 1 hour. You will learn about different topics and practice skills at each class to prepare you for managing your diabetes self-care activities in the community.

During the 1-hour education sessions, there will be opportunities for you to talk with the other participants, a student nurse, and with me, the diabetes educator. You will be given educational pamphlets with information about the topic of the week and a workbook page that includes questions about taking care of your diabetes. I will ask you to complete the workbook page and return it to me at the next scheduled class. You do not have to answer any questions that you do not want to answer.

Visit 3-6: The next 4 educational sessions will be 1 hour and will include education and discussion only. We will review the workbook pages and practice skills such as glucose monitoring, medication taking, and healthy eating during each session. The CO will call you to each of the meetings and escort you back to your living quarters at the end of each session.

Visit 7: This session will proceed exactly as session 2. We will meet for 90 minutes to participate in the final education session and complete 4 surveys/questionnaires. At this session, I will again ask you to participate in

weekly one-hour support groups with other interested participants. These sessions will start at a date and time decided by the Connecticut Department of Corrections (CT DOC).

Visit 8: Two weeks after the completion of the last education session, you will be contacted to participate in a 1.5-2-hour focus group meeting with the PI, a student member of the research team and 8-10 study participants. During this meeting, I will ask you questions about how satisfied you were with the program, what you liked or did not like about the program, and other questions that will help me to hear your thoughts and opinion about the Diabetes Survival Skills program.

Visit 9: We will meet for 45-60 minutes to complete the same 4 questionnaires that you completed during visit 2.

Visit 10+: If you agree, you and other participants of the study will meet to discuss diabetes related issues of interest to you. Participation in these groups is voluntary and may be stopped at any time or you can miss a session and join the next session a week later. The PI will help with the flow and coordination of the support group but there will be no formal discussion or specific topic planned.

Here is a diagram showing a rough estimate of the schedule of study visits.

Visit 1→	Visit 2 →	Visit 3-6→	Visit 7 →	Visit 8 →	Visit 9 →	Visit 10+
Today 1.5 hours	Week 4 1.5 hour	Week 5-8 1 hour	Week 9 1.5 hours	Week 11 2 hours Focus Group	Week 15 1 hour	Weeks 16+ 1hour /week optional
Consent Complete 3 forms	Complete 4 forms Class 1	Classes 2-5	Complete 4 forms Class 6		Complete 4 forms	Support Group

We will only meet once for the Focus group (Visit 8) unless I need to ask you more about something you said during the first interview. In this case, one (1) follow-up interview may be needed to clarify something that you said. With your permission I will contact you by mail to request this interview.

During the focus group, the student assistant will take notes and a pocket sized audio(tape) recorder will be used to audiotape the Focus group interview.

- The recording is to make sure that I record exactly what you and the other participants said during the interview.
- Only approved members of the research team listen to the audiotape to type (transcribe) what you said.
- There will be no identifying information on the recording or the typed report.
- If you choose not to be audiotaped, you will not be able to participate in the focus group with the other participants.
- If you agree to being audiotaped but feel uncomfortable at any time during the interview, I can turn off the recorder at your request. Or if you don't wish to continue, you can stop the interview at any time.

After the interview is over, you and the other participants will be thanked for your time and escorted back to your living quarters. At this time, you may continue participation in the weekly or bi-weekly diabetes support group. Depending on attendance at the support group, the group may meet weekly or bi-weekly. These sessions will start at a date and time decided by the CT DOC. You will be notified of the schedule at least one day before the support group meeting.

In the event you are released from incarceration prior to completing the DSS study and educational program, you have the option to give the CTDOC permission to release your contact information to the PI. This information will be used by the PI to contact you and make arrangements to provide you the handouts and workbook pages from the diabetes classes you will miss, and the glucose meter you should receive for participating in the program. We will answer any of your diabetes related questions.

In addition, when we meet or talk on the phone, if you agree, you will complete surveys you were unable to complete because of your release. If you agree to complete the surveys, a member of the research team will contact once or twice (about 6 weeks and 12 weeks after you completed the program) to compete the surveys. You will have the option to complete the surveys on the phone with the PI or member of the research team or arrange to meet the PI at a local library to complete the surveys. The decision to participate in the surveys will not affect your ability to receive the educational handouts, the glucometer, and your certificate of completion.

If you agree to be contacted after you are released from prison, you will meet or speak with a member of the research team at most an additional 1-3 visits to receive your glucose meter and education handouts, and complete 4 surveys.

What other options are there?

There are no other options.

What are the risks or inconveniences of the study?

The risks involved with taking part in this study are low. Being in the study is strictly voluntary. There is a chance that your confidentiality can be compromised; however, we are taking safety measures to lower this risk.

One possible inconvenience is the time commitment to the study. You will meet with the PI on 9 occasions during the course of study or more should you decide to participate in the support group or meet with a member of the researcher team after you have been released from prison. The meetings will last about 1-2 hours. But you can take a break, if you do not want to answer a question or you feel uncomfortable or become tired. You are free to skip a question or stop the meeting for any reason.

What are the benefits of the study?

There will be no direct benefit to you from your participation. Your help in this study may help us to develop and plan diabetes education for incarcerated persons preparing for release into the community.

Will I receive payment for participation? Are there costs to participate?

You do not pay. You will not receive any compensation or payment for being in in this study. You will be able to take the glucose meter used in class home with you when you are released from prison.

How will my personal information be protected?

Only the principal investigator (Louise Reagan), and approved members of the research team will have access to the information obtained during the study. If a person is used to type what is on the audiotape, he will have access to the information on the recording and be an approved member of the research team. There will no information on the recording that personally identifies you.

At the conclusion of this study, the researchers may publish their findings and

present findings in a professional magazine or at a conference. The Information will be presented in summary format and you will not be identified in any publications or presentations.

All research team members are current in Human Subjects certifications. All consent forms, surveys, and study data are retained on a secure computer which will be in a locked office at UConn School of Nursing accessible only to team members. A password coded file will be created using unique identifiers linking components of the data. Once the data are analyzed, the list linking the subject identifiers and names will be destroyed. Investigators must maintain research records for three years beyond the completion/termination of the study.

(Audio)Tapes will not identify study participants and will be transcribed into WORD file. Audiotapes will be secured in a locked file cabinet at the University of Connecticut school of nursing. Following transcription, the audiotapes will be erased. All transcribed data will be saved to a password protected University of Connecticut research computer.

Questionnaire data will be entered into an EXCEL or computer spreadsheet with no personally identifiable information. All research data files will be password encrypted/protected with access through password protected University of Connecticut computers. All paper forms will be retained in a secured locked file at the University of Connecticut.

You should also know that the UConn Institutional Review Board (IRB) and the Office of Research Compliance may inspect study records. These reviews will only focus on the researchers and not on your responses or involvement. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

Your records will be maintained in accordance with state and federal laws. We will do our best to protect the confidentiality of the information we gather from you but we cannot guarantee I 00% confidentiality.
In the event of being released from incarceration prior to completing the DSS educational program, you have the option to give the CTDOC permission to release contact information to the PI. This contact information will be maintained in a password protected file on the principle investigator's office computer at the University of Connecticut along with other identified research documents.

Can I stop being in the study and what are my rights?

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. No one will treat you differently. You will not be penalized. Your participation will have no effect on your parole or your release from prison.

There are no penalties or consequences of any kind if you decide that you do not want to participate. You do not have to answer any question that you do not want to answer.

You may be removed from the study if you are placed in administrative segregation, the hospital, or demonstrate any illegal behavior or your primary clinician or administration at the CT DOC thinks you should be removed for safety reasons.

Whom do I contact if I have questions about the study?

Take as long as you like before you make a decision. We will be happy to answer any question you have about this study. If you have further questions about this study or if you have a research-related problem, you may contact the principal investigator, (Dr. Louise Reagan at louise.reagan@uconn.edu or 860-486-0593, or by mail: University of Connecticut, School of Nursing, 231 Glenbrook Rd., Storrs, CT 06269-4026. If you have any questions concerning your rights as a research participant, you may contact the University of Connecticut Institutional Review Board (IRB) at irb@uconn.edu.

Documentation of Consent:

By signing the document, you are saying:

- You agree to be in the study.
- We talked with you about the information in this document and answered all your questions.
- you are giving the CTDOC permission to release (give) your contact information to the PI for the reasons stated in this document for the purpose of contacting you after you have been released from prison.

You know that:

- You can skip questions you do not want to answer.
- You can stop answering our questions at any time and nothing will happen to you.

You can call the office in charge of research at 860-486-8802if you have any questions about the study or about your rights. I have read this form and decided that I will participate in the project described above. Its general purposes, the particulars of involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time. My signature also indicates that I have received a copy of this consent form.

_____	_____	_____
Participant Signature:	Print Name:	Date:
_____	_____	_____
Signature of Person Obtaining Consent	Print Name:	Date:

Consent Form for Participation in a Research Study

UCONN
UNIVERSITY OF CONNECTICUT

Principal Investigator: Louise Reagan, PhD
Study Title: A Study to Evaluate the Feasibility and Acceptability of a Diabetes Survival Skills + (DSS+) Intervention for Incarcerated Persons Transitioning to the Community (TTC)

Introduction

I am faculty member in the School of Nursing at the University of Connecticut.

You are asked to help us determine if a diabetes education program called Diabetes Survival Skills+ (DSS+) is acceptable to incarcerated person preparing for release from prison. The diabetes survival skills education is a six session program designed to provide you with the basic survival skills such as understanding the basic facts about diabetes, and taking diabetes medications or insulin, testing and keeping track of your blood sugar, recognizing and treating low blood sugar or hypoglycemia, and how to eat healthy and make an appointment with a doctor or nurse practitioner who will help you care for diabetes upon release from prison. We are also interested in learning if this diabetes education program has an effect on what you know and believe about diabetes, your confidence level in taking care of your diabetes, and your stress associated with diabetes.

A grant from the University of Connecticut's Office of the Vice President for Research (OVPR)will provide some funding for this study. The funding will be used to pay for a nursing student to assist me with the study, education materials, and a statistician to help with analyzing the information obtained from questionnaires completed by the participants.

You are being asked to participate because you have diabetes and you will be released from prison within the next 6-9 months.

- You do not have to be in the study.
- If you say yes, you can quit at any time.
- Please take as much time as you need to make your decision.

- Your medical care will not change in any way if you say no.

Why is this study being done?

We want to learn more about what type of education program helps incarcerated persons to be prepared for managing diabetes when no longer incarcerated.

We will use this information to plan diabetes education for incarcerated persons with diabetes leaving prison to help prepare them to care for diabetes while living in the community.

What will I be asked to do?

If you agree to be in the study, we will meet 4 times including today over a period of 14 weeks. After 14 weeks, you may participate in a diabetes education program with 10-12 additional incarcerated persons for 1 hour once weekly for 6 weeks.

Visit 1: we will meet for 90 minutes or less at the correctional facility where you live. After you agree to be in the study and sign this document, you will be asked to complete 3 forms. I will read questions aloud asking you:

- your age, highest grade completed in school, gender, date of release from prison, how long you were in prison, type of diabetes, medical history and medications, whether you have use or have used alcohol or drugs, and if or when you have participated in a diabetes education class.
- to read information about health and answer a few questions about what you read.
- to draw objects, and recall name of objects that are shown to you.
- You do not have to answer any questions that you do not want to answer. There are no right or wrong answers to these questions.
- If you cannot name all of your medications and medical conditions, I will ask you to sign a permission slip (HIPAA release) allowing me to look at your medical and pharmacy record to obtain a list of your medications and medical conditions (illnesses) and obtain your contact information from the CDOC should you be released prior to completion of the studyYou can refuse this request. Because we need an accurate list of your medications and medical conditions, you will not be able to participate in the study if you prefer that we not look at your medical record.
- After you have completed all 3 forms, the Officer will escort you to your living area.

Visit 2: Within the month following visit 1, we will meet for 60 minutes in a room at the correctional facility with 10-12 other incarcerated persons with diabetes who are also participating in the study. You will be asked to complete 4 questionnaires. I will read the surveys aloud to you and the other participants. You will be asked questions about:

- what you know about diabetes.
- how confident you feel about caring for your diabetes.
- your beliefs about diabetes
- the level of concern or stress you feel about diabetes and diabetes self-care tasks.

After you complete the surveys, the Officer will escort you to your living area. .

Visit 3: Six weeks after visit 2 (week 9), We will meet for 60 minutes to complete the same 4 questionnaires that you completed during visit 2. After you complete the surveys, the Officer will escort you to your living area.

Visit 4: Six weeks after visit 3 (week 19), We will meet for 60 minutes to complete the same 4 questionnaires that you completed during visit 2 and 3. After you complete the surveys, the Officer will escort you to your living area. You will receive a Certificate of Participation for completing the study.

After completing visits 1-4, You will have the option to participate in a 1 hour 6-session once weekly diabetes education program to prepare you for reentering the community. The diabetes education class will start 1 week after the completion of visit 4.

If you choose to participate in the class, You will learn about different topics and practice skills at each class to prepare you for managing your diabetes self-care activities in the community.

During the 1-hour education sessions, there will be opportunities for you to talk with the other participants, a student nurse, and with me, the diabetes educator. You will be given educational pamphlets with information about the topic of the week and a workbook page that includes questions about taking care of your diabetes. I will ask you to complete the workbook page and return it to me at the next scheduled class. You do not have to answer any questions that you do not want to answer.We will review the workbook pages and practice skills such as glucose monitoring, medication taking, and healthy eating during each session. The CO will call you to each of the meetings and

escort you back to your living quarters at the end of each session.

If you are going to be released from prison or transferred to another facility before you complete the diabetes classes, we will arrange to meet with you provide you the handouts and workbook pages from the diabetes classes you will miss. And, we will answer any of your diabetes related questions.

In the event you are released from incarceration prior to completing the DSS study educational program, you have the option to sign a HIPPA release giving the CTDOC permission to release your contact information to the PI. This information will be used by the PI to contact you and arrange to provide you with the educational materials, and the glucometer you should receive for participating in the program and if you agree to complete surveys you were unable to complete because of your release. If you agree to complete the surveys, a member of the research team will contact once or twice (about 6 weeks and 12 weeks after you completed the program) to compete the surveys. You will have the option to complete the surveys on the phone with the PI or member of the research team or arrange to meet the PI at a local library to complete the surveys. The decision to participate in the surveys will not affect your ability to receive the educational materials, the glucometer, and your certificate of completion.

If you agree to be contacted after you are released from prison, you will meet or speak with a member of the research team at most an additional 1-3 visits to receive your glucose meter and education handouts, and complete 4 surveys.

Here is a diagram showing a rough estimate of the schedule of study visits.

Visit 1 → (optional)	Visit 2 →	Visit 3 →	Visit 4 →	Visit 5-10
Today 1.5 hours	Week 4 1 hour	Week 9 1 hour	Week 15 1 hour	Week 15-20 1 hour /week
Consent Complete 3 forms	Complete 4 forms	Complete 4 forms	Complete 4 forms	Diabetes Classes

What other options are there?

There are no other options.

What are the risks or inconveniences of the study?

The risks involved with taking part in this study are low. Being in the study is strictly voluntary. There is a chance that your confidentiality can be compromised; however, we are taking safety measures to lower this risk.

One possible inconvenience is the time commitment to the study. You will meet with the PI 4 times during the course of study. The meetings will last about 1-2 hours. But you can take a break if you do not want to answer a question or you feel uncomfortable or become tired. You are free to skip a question or stop the meeting for any reason.
Additionally, you will be asked to wait 12 weeks before participating in the diabetes education class. You may not want to wait to participate in the diabetes education classes. You may decline participation or stop participation at any time.

What are the benefits of the study?

There will be no direct benefit to you from your participation. Your help in this study may help us to develop and plan diabetes education for incarcerated persons preparing for release into the community.

Will I receive payment for participation? Are there costs to participate?

You do not pay. You will not receive any compensation or payment for being in in this study. You will be able to take the glucose meter used in class home with you when you are released from prison.

How will my personal information be protected?

Only the principal investigator (Louise Reagan), and approved members of the research team will have access to the information obtained during the study.

At the conclusion of this study, the researchers may publish their findings and present findings in a professional magazine or at a conference. The Information will be presented in summary format and you will not be identified in any publications or presentations.

All research team members are current in Human Subjects certifications. All consent forms, surveys, and study data are retained on a secure computer which

will be in a locked office at UConn School of Nursing accessible only to team members. A password coded file will be created using unique identifiers linking components of the data. Once the data are analyzed, the list linking the subject identifiers and names will be destroyed. Investigators must maintain research records for three years beyond the completion/termination of the study.

Questionnaire data will be entered into an EXCEL or computer spreadsheet with no personally identifiable information. All research data files will be password encrypted/protected with access through password protected University of Connecticut computers. All paper forms will be retained in a secured locked file at the University of Connecticut.

You should also know that the UConn Institutional Review Board (IRB) and the Office of Research Compliance may inspect study records. These reviews will only focus on the researchers and not on your responses or involvement. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

Your records will be maintained in accordance with state and federal laws. We will do our best to protect the confidentiality of the information we gather from you but we cannot guarantee I 00% confidentiality."

Can I stop being in the study and what are my rights?

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. No one will treat you differently. You will not be penalized. Your participation will have no effect on your parole or your release from prison.

There are no penalties or consequences of any kind if you decide that you do not want to participate. You do not have to answer any question that you do not want to answer.

You may be removed from the study if you are placed in administrative segregation, the hospital, or demonstrate any illegal behavior or your primary clinician or administration at the CT DOC thinks you should be removed for safety reasons.

Whom do I contact if I have questions about the study?

Take as long as you like before you make a decision. We will be happy to answer any question you have about this study. If you have further questions about this study or if you have a research-related problem, you may contact the principal investigator, (Dr. Louise Reagan at louise.reagan@uconn.edu or 860-486-0593, or by mail: University of Connecticut, School of Nursing, 231 Glenbrook Rd., Storrs, CT 06269-4026. If you have any questions concerning your rights as a research participant, you may contact the University of Connecticut Institutional Review Board (IRB) at irb@uconn.edu.

Documentation of Consent:

By signing the document, you are saying:

- You agree to be in the study.
- We talked with you about the information in this document and answered all your questions.

You know that:

- You can skip questions you do not want to answer.
- You can stop answering our questions at any time and nothing will happen to you.

You can call the office in charge of research at 860-486-8802if you have any questions about the study or about your rights. I have read this form and decided that I will participate in the project described above. Its general purposes, the particulars of involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time. My signature also indicates that I have received a copy of this consent form.

_____ _____ _____

Participant Signature: Print Name: Date:

_____	_____	_____
Signature of Person Obtaining Consent	Print Name:	Date:

Consent Form for Participation in a Research Study

UCONN
UNIVERSITY OF CONNECTICUT

Principal Investigator: Louise Reagan, PhD
Study Title: A Study to Evaluate the Feasibility and Acceptability of a Diabetes Survival Skills + (DSS+) Intervention for Incarcerated Persons Transitioning to the Community (TTC)

Introduction

I am faculty member in the School of Nursing at the University of Connecticut.

You are asked to help us determine if a diabetes education program called Diabetes Survival Skills+ (DSS+) is acceptable to incarcerated person preparing for release from prison. The diabetes survival skills education is a six session program designed to provide you with the basic survival skills such as understanding the basic facts about diabetes, and taking diabetes medications or insulin, testing and keeping track of your blood sugar, recognizing and treating low blood sugar or hypoglycemia, and how to eat healthy and make an appointment with a doctor or nurse practitioner who will help you care for diabetes upon release from prison. We are also interested in learning if this diabetes education program has an effect on what you know and believe about diabetes, your confidence level in taking care of your diabetes, and your stress associated with diabetes.

A grant from the University of Connecticut's Office of the Vice President for Research (OVPR)will provide some funding for this study. The funding will be used to pay for a nursing student to assist me with the study, education materials, and a statistician to help with analyzing the information obtained from questionnaires completed by the participants.

You are being asked to participate because you have diabetes and you will be released from prison within the next 6-9 months.

- You do not have to be in the study.
- If you say yes, you can quit at any time.
- Please take as much time as you need to make your decision.

- Your medical care will not change in any way if you say no.

Why is this study being done?

We want to learn more about what type of education program helps incarcerated persons to be prepared for managing diabetes when no longer incarcerated.

We will use this information to plan diabetes education for incarcerated persons with diabetes leaving prison to help prepare them to care for diabetes while living in the community.

What will I be asked to do?

If you agree to be in the study, we will meet 4 times including today over a period of 14 weeks. After 14 weeks, you may participate in a diabetes education program with 10-12 additional incarcerated persons for 1 hour once weekly for 6 weeks.

Visit 1: we will meet for 90 minutes or less at the correctional facility where you live. After you agree to be in the study and sign this document, you will be asked to complete 3 forms. I will read questions aloud asking you:

- your age, highest grade completed in school, gender, date of release from prison, how long you were in prison, type of diabetes, medical history and medications, whether you have use or have used alcohol or drugs, and if or when you have participated in a diabetes education class.
- to read information about health and answer a few questions about what you read.
- to draw objects, and recall name of objects that are shown to you.
- You do not have to answer any questions that you do not want to answer. There are no right or wrong answers to these questions.
- If you cannot name all of your medications and medical conditions, I will ask you to sign a permission slip (HIPAA release) allowing me to look at your medical and pharmacy record to obtain a list of your medications and medical conditions (illnesses) and obtain your contact information from the CDOC should you be released prior to completion of the studyYou can refuse this request. Because we need an accurate list of your medications and medical conditions, you will not be able to participate in the study if you prefer that we not look at your medical record.
- After you have completed all 3 forms, the Officer will escort you to your living area.

Visit 2: Within the month following visit 1, we will meet for 60 minutes in a room at the correctional facility with 10-12 other incarcerated persons with diabetes who are also participating in the study. You will be asked to complete 4 questionnaires. I will read the surveys aloud to you and the other participants. You will be asked questions about:

- what you know about diabetes.
- how confident you feel about caring for your diabetes.
- your beliefs about diabetes
- the level of concern or stress you feel about diabetes and diabetes self-care tasks.

After you complete the surveys, the Officer will escort you to your living area. .

Visit 3: Six weeks after visit 2 (week 9), We will meet for 60 minutes to complete the same 4 questionnaires that you completed during visit 2. After you complete the surveys, the Officer will escort you to your living area.

Visit 4: Six weeks after visit 3 (week 19), We will meet for 60 minutes to complete the same 4 questionnaires that you completed during visit 2 and 3. After you complete the surveys, the Officer will escort you to your living area. You will receive a Certificate of Participation for completing the study.

After completing visits 1-4, You will have the option to participate in a 1 hour 6-session once weekly diabetes education program to prepare you for reentering the community. The diabetes education class will start 1 week after the completion of visit 4.

If you choose to participate in the class, You will learn about different topics and practice skills at each class to prepare you for managing your diabetes self-care activities in the community.

During the 1-hour education sessions, there will be opportunities for you to talk with the other participants, a student nurse, and with me, the diabetes educator. You will be given educational pamphlets with information about the topic of the week and a workbook page that includes questions about taking care of your diabetes. I will ask you to complete the workbook page and return it to me at the next scheduled class. You do not have to answer any questions that you do not want to answer.We will review the workbook pages and practice skills such as glucose monitoring, medication taking, and healthy eating during each session. The CO will call you to each of the meetings and

escort you back to your living quarters at the end of each session.

If you are going to be released from prison or transferred to another facility before you complete the diabetes classes, we will arrange to meet with you provide you the handouts and workbook pages from the diabetes classes you will miss. And, we will answer any of your diabetes related questions.

In the event you are released from incarceration prior to completing the DSS study educational program, you have the option to sign a HIPPA release giving the CTDOC permission to release your contact information to the PI. If you anticipate release before completion of the diabetes classes, you may also choose to provide the study team with contact information before your release. This information will be used by the PI to contact you and arrange to provide you with the educational materials, and the glucometer you should receive for participating in the program and if you agree to complete surveys you were unable to complete because of your release. If you agree to complete the surveys, a member of the research team will contact once or twice (about 6 weeks and 12 weeks after you completed the program) to compete the surveys. You will have the option to complete the surveys on the phone with the PI or member of the research team or arrange to meet the PI at a local library to complete the surveys. The decision to participate in the surveys will not affect your ability to receive the educational materials, the glucometer, and your certificate of completion.

If you agree to be contacted after you are released from prison, you will meet or speak with a member of the research team at most an additional 1-3 visits to receive your glucose meter and education handouts, and complete 4 surveys.

Here is a diagram showing a rough estimate of the schedule of study visits.

Visit 1 → (optional)		Visit 2 →	Visit 3 →	Visit 4 → Visit 5-10
Today 1.5 hours	Week 4 1 hour	Week 9 1 hour	Week 15 1 hour	Week 15-20 1 hour /week
Consent Complete 3 forms	Complete 4 forms	Complete 4 forms	Complete 4 forms	Diabetes Classes

What other options are there?

There are no other options.

What are the risks or inconveniences of the study?

The risks involved with taking part in this study are low. Being in the study is strictly voluntary. There is a chance that your confidentiality can be compromised; however, we are taking safety measures to lower this risk.

One possible inconvenience is the time commitment to the study. You will meet with the PI 4 times during the course of study. The meetings will last about 1-2 hours. But you can take a break if you do not want to answer a question or you feel uncomfortable or become tired. You are free to skip a question or stop the meeting for any reason.
Additionally, you will be asked to wait 12 weeks before participating in the diabetes education class. You may not want to wait to participate in the diabetes education classes. You may decline participation or stop participation at any time.

What are the benefits of the study?

There will be no direct benefit to you from your participation. Your help in this study may help us to develop and plan diabetes education for incarcerated persons preparing for release into the community.

Will I receive payment for participation? Are there costs to participate?

You do not pay. You will not receive any compensation or payment for being in in this study. You will be able to take the glucose meter used in class home with you when you are released from prison.

How will my personal information be protected?

Only the principal investigator (Louise Reagan), and approved members of the research team will have access to the information obtained during the study.

At the conclusion of this study, the researchers may publish their findings and present findings in a professional magazine or at a conference. The Information will be presented in summary format and you will not be identified in any publications or presentations.

All research team members are current in Human Subjects certifications. All consent forms, surveys, and study data are retained on a secure computer which will be in a locked office at UConn School of Nursing accessible only to team members. A password coded file will be created using unique identifiers linking components of the data. Once the data are analyzed, the list linking the subject identifiers and names will be destroyed. Investigators must maintain research records for three years beyond the completion/termination of the study.

Questionnaire data will be entered into an EXCEL or computer spreadsheet with no personally identifiable information. All research data files will be password encrypted/protected with access through password protected University of Connecticut computers. All paper forms will be retained in a secured locked file at the University of Connecticut.

You should also know that the UConn Institutional Review Board (IRB) and the Office of Research Compliance may inspect study records. These reviews will only focus on the researchers and not on your responses or involvement. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

Your records will be maintained in accordance with state and federal laws. We will do our best to protect the confidentiality of the information we gather from you but we cannot guarantee I 00% confidentiality."

Can I stop being in the study and what are my rights?

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. No one will treat you differently. You will not be penalized. Your participation will have no effect on your parole or your release from prison.

There are no penalties or consequences of any kind if you decide that you do not want to participate. You do not have to answer any question that you do not want to answer.

You may be removed from the study if you are placed in administrative segregation, the hospital, or demonstrate any illegal behavior or your primary clinician or administration at the CT DOC thinks you should be removed for

safety reasons.

Whom do I contact if I have questions about the study?

Take as long as you like before you make a decision. We will be happy to answer any question you have about this study. If you have further questions about this study or if you have a research-related problem, you may contact the principal investigator, (Dr. Louise Reagan at louise.reagan@uconn.edu or 860-486-0593, or by mail: University of Connecticut, School of Nursing, 231 Glenbrook Rd., Storrs, CT 06269-4026. If you have any questions concerning your rights as a research participant, you may contact the University of Connecticut Institutional Review Board (IRB) at irb@uconn.edu.

Documentation of Consent:

By signing the document, you are saying:

- You agree to be in the study.
- We talked with you about the information in this document and answered all your questions.

You know that:

- You can skip questions you do not want to answer.
- You can stop answering our questions at any time and nothing will happen to you.

You can call the office in charge of research at 860-486-8802if you have any questions about the study or about your rights. I have read this form and decided that I will participate in the project described above. Its general purposes, the particulars of involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time. My signature also indicates that I have received a copy of this consent form.

Participant Signature:	Print Name:	Date:
_____	_____	_____
Signature of Person Obtaining Consent	Print Name:	Date: