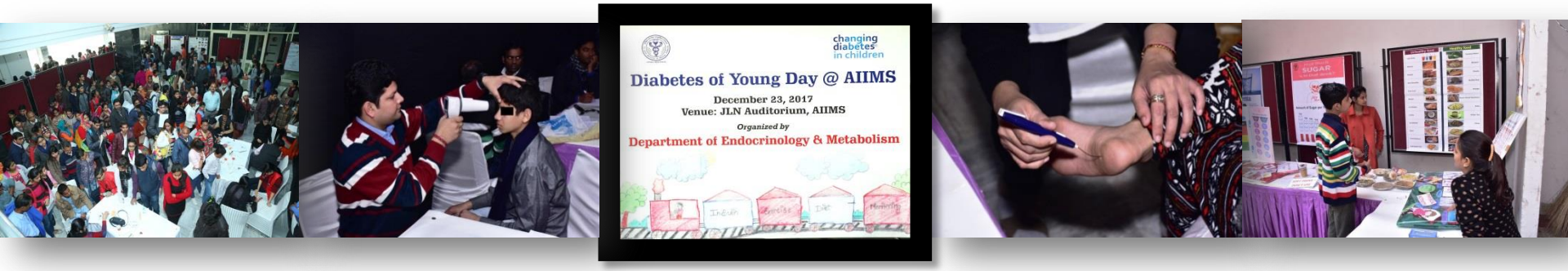
Effectiveness of a structured Paediatric to Adult management Transition intervention for the Health and Wellness of Youth onset diabetes in India [PATHWAY-INDIA Trial]



Praveen Pradeep, MPH, PhD

Scientist-C

Department of Endocrinology and Metabolism

All India Institute of medical Sciences (AIIMS), New Delhi

Background-1

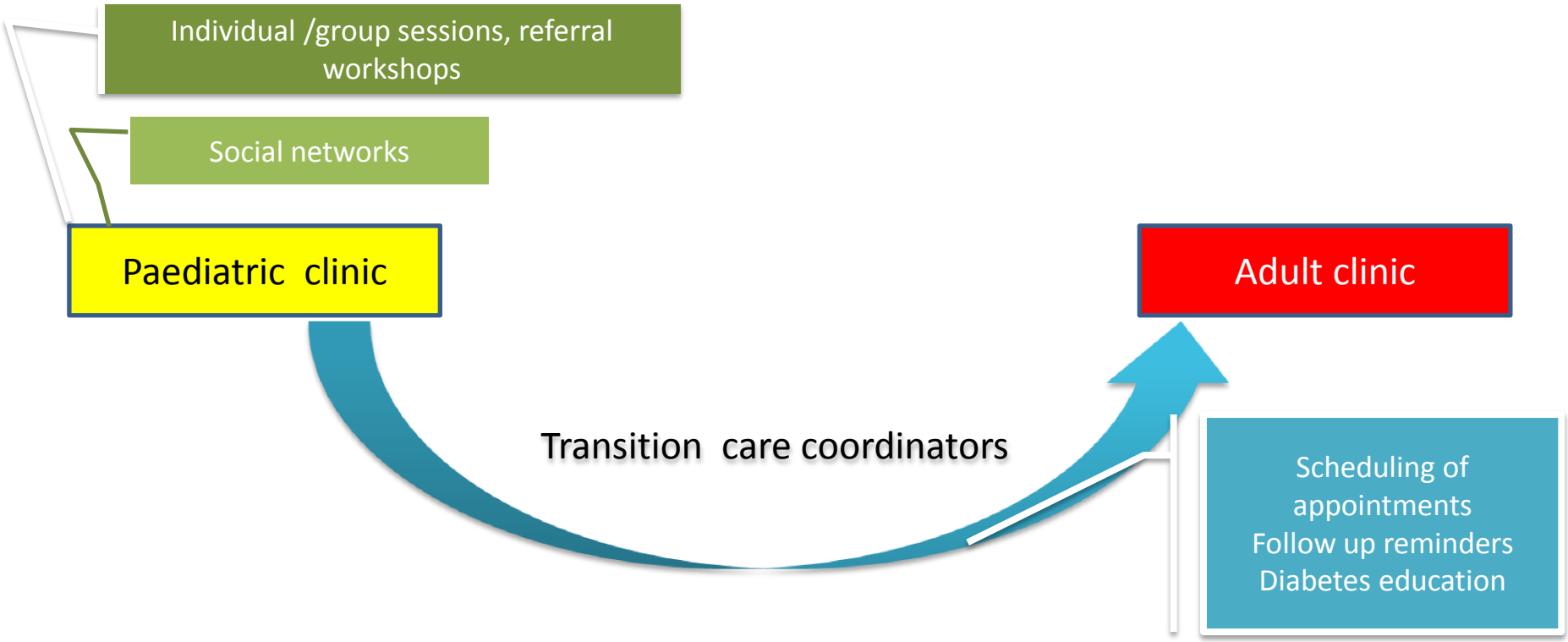
- Substantial gap in management of diabetes during transition from paediatric to adult care.
- Globally, one third of young people with T1DM were not transferred to an adult diabetes service within six months of leaving paediatric care.
- India, tertiary hospital data: only 6% of the adolescent patients leaving paediatric care transferred to the adult care clinic located in the same centre.

Background-2

- Factors that hamper successful transition include:
  - lack of facilitated referral
  - poor access to paediatric records
  - lack of behavioural health services
  - competing individual priorities
  - less parental education
  - changing social and demographic characteristics
  - differences in health care delivery
  - lack of well-defined criteria for determination of transition readiness

- Abrupt transfer to an adult clinic, subsequent attrition from diabetes care leads to poor metabolic control and adverse health outcomes

Models of transition care-summary of literature



Sample sizes most studies <100

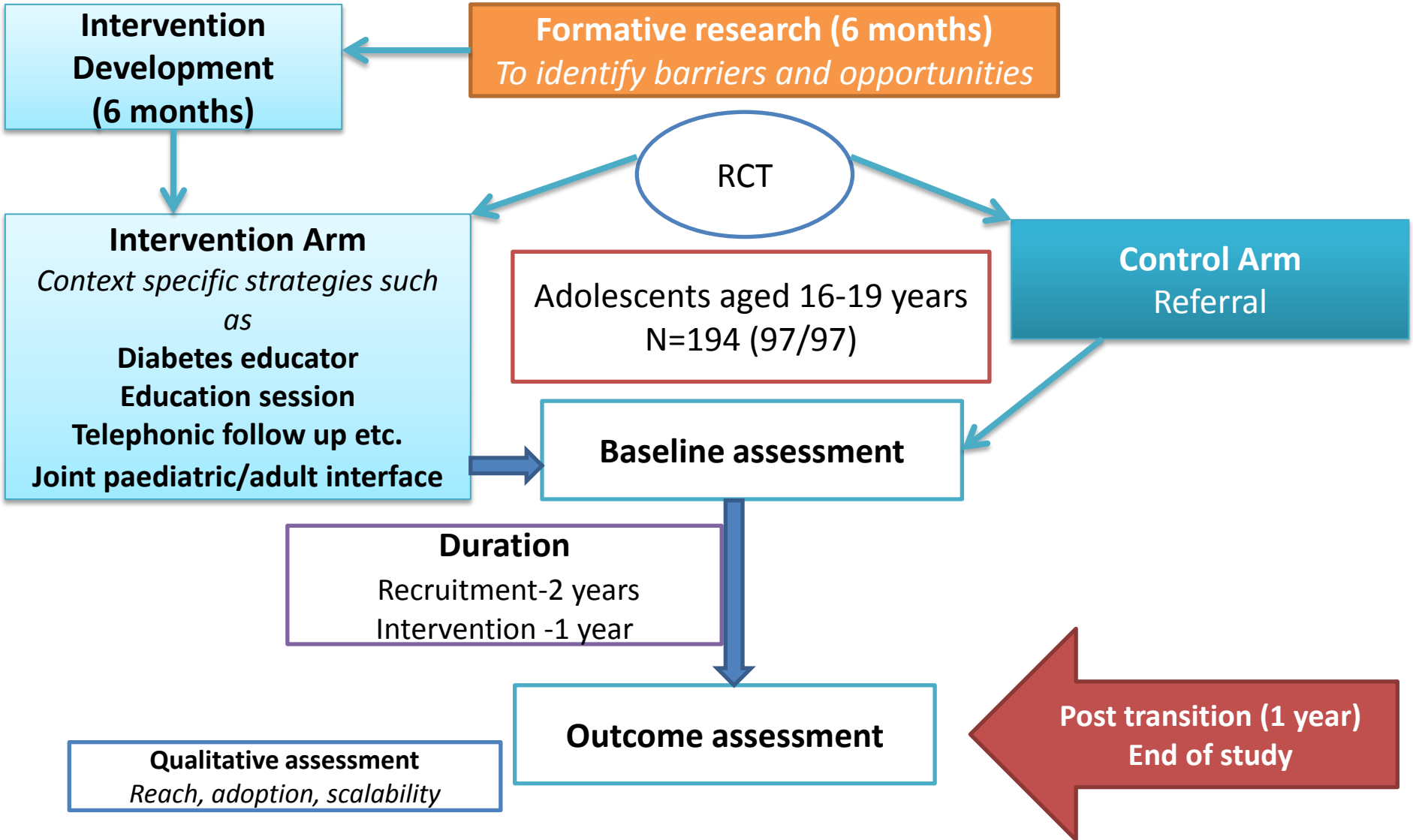
Studies used combination of above strategies

Average age of transition- 17 years

Dearth of empirical evidence on the best approaches to the transition process (selection bias; lack of comparison groups)

Limited RCT evidence; none from LMIC!!

Trial Design



Study description

- **Aim:**
  - To identify the barriers and opportunities for the transition of paediatric to adult care among patients with T1DM
  - To develop a structured paediatric to adult management transition intervention to improve adherence to diabetes care and clinical outcomes among patients with T1DM
  - To test effectiveness of the above intervention

- **Study design:** Open label randomized controlled trial, with mixed methods evaluation
- **Study setting:** Selected paediatric and adult diabetes clinics from Delhi NCR

Formative research

- Mapping of clinics/hospitals (both paediatric and adult) with facilities to manage patients with T1DM at Delhi NCR

In selected hospitals/clinics:

- Focus group discussion (8-12 participants each) among patients and care givers:
  - Participants will be asked to describe their life experience with T1DM
  - Describe a supporting environment for successful transition

- In-depth interviews among paediatricians, adult diabetes care providers, hospital administrators and diabetes educators/nurses;
  - Stake holders will be asked to describe the capabilities, opportunities and perceived barriers in relation to the intervention
- Desktop review and participant observation to understand the diabetes care process at the study sites

Intervention

- **<u>Core components of the intervention:</u>**
  - Transition preparedness: paediatric care provider/ diabetes educators
  - Diabetes education: content, frequency, mode (individual/group sessions)
  - Transition pathway: paediatric to adult/paediatric to transition clinic/paediatric to young adult diabetes clinic etc.
  - Follow up reminders

- MRC guidelines and RE-AIM framework: Designing of intervention

- The final **intervention package** will be largely influenced by the proposed formative research
- **Duration of intervention:** 1 year
- Minimum follow up: 1 year
- **Control arm** will receive an initial “one-to-one” counselling and guidance on referral care

- **Study population and Inclusion criteria (RCT):**
  - Established T1DM diagnosis for a minimum of one year
  - Age 16-19 years
  - At least one visit during the previous year with the pediatric care provider at the participating centre
  - Ability to participate in all aspects of the clinical trial
  - Written informed consent/assent must be obtained and documented (as per ICMR guidelines 2017)
  - Resident of Delhi NCR
- **Exclusion criteria:**
  - Pregnant or lactating females or intent to become pregnant during the next 3 years
  - Participation in another clinical trial: current or within 6 months prior to enrolment
  - Condition(s) which in the opinion of the investigator may interfere with the subject's ability to participate in the study

Randomization and Allocation

Randomization	Randomization will occur between 6-12 months prior to the proposed date of transition at the paediatric diabetes care facility
Allocation sequence generation	Mixed block randomization (site and A1c) using nQuery software.
Allocation concealment	Central allocation: software / telephonic
Blinding	Open label, objective assessment of outcomes, data analysis personnel will be blinded to the group assignment.

Primary outcome-RCT

- Post transition difference between the intervention and control groups in terms of a composite outcome of process of care, behavioural and biomedical endpoints.

•Post transition clinic attendance rate • Adherence to diabetes care •Proportion undergoing diabetes complication screening •Quality of life	•Post transition glycaemic control •Incidence of severe hypoglycemia •Incidence of Diabetic ketoacidosis •Incidence of Hospitalization

- The variables for the primary outcome model will be finalized after the formative research

We will validate the above theoretical model by *Pierce and Wysocki* (*Journal of Pediatric Psychology, 40(10), 2015, 1041–1047)* through formative research and will propose a composite outcome model to evaluate the transition of care.

RE-AIM indicators

Reach	Estimates of the absolute number, proportion and representativeness of individuals willing to participate in the intervention
Effectiveness	Primary outcome measures
Adoption	Proportion of patients/care givers who report satisfaction with the intervention Proportion of clinicians/diabetes educators/hospital administrators who report satisfaction with the intervention
Implementation	Number of diabetes education sessions delivered Number of above sessions attended Number of follow-up reminders and patient response
Maintenance	Views of program sustainability and barriers to sustaining and disseminating the program (qualitative)

www.re-aim.org

Sample size calculation-RCT

Assumptions

- Post transition clinic attendance rate;
  - Control-60%*
  - Intervention group-80%
- Alpha error of 5% for 80% study power
- Estimated sample size in one group=81
- Enrollment ratio=1:1
- Non response rate in the intervention phase=20%
- Final sample size=97+ 97=194

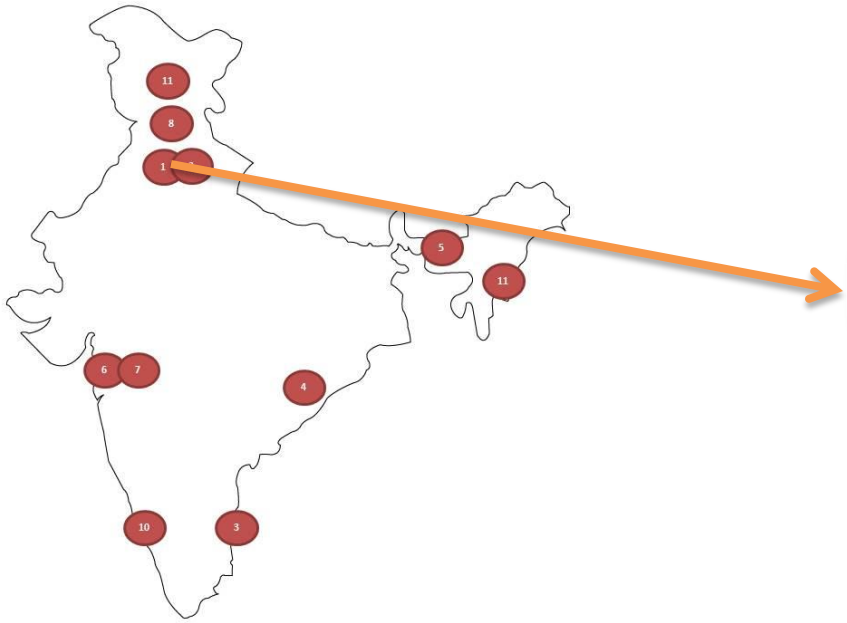
** YDR follow up data*

Assessment plan

	Baseline (randomization)	Post intervention (1 year)	End of study
Demographic characteristics	x		
Visit attendance		x	x
Adherence to diabetes care (Morisky questionnaire)	x	x	x
Self care practices (SMBG, foot examination)	x	x	x
Quality of life questionnaire	x	x	x
Proportion undergoing diabetes complication screening		x	x
Diabetes treatment satisfaction questionnaire	x	x	x
Diabetes distress questionnaire	x	x	x
DKA (Emergency visit)-past one year	x	x	x
Hypoglycemia events-past one year	x	x	x
HbA1c	x	x	x
Reach, adoption, implementation and maintenance indicators			x

YDR registry-India

YDR collaborating centres



YDR reporting centres

RCC01-All India Institute of Medical Sciences (AIIMS), New Delhi; RCC02- University College of Medical Sciences (UCMS), New Delhi; RCC03- Madras Diabetes Research Foundation (MDRF), Chennai; RCC04-SCB Medical College, Cuttack; RCC05- Assam Medical College (AMC), Dibrugarh; RCC06- KEM hospital, Mumbai; RCC07- P.D Hinduja hospital, Mumbai; RCC08- Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh; RCC09-Regional Institute of Medical Sciences, Imphal; RCC10-KMC,Manipal; RCC11-Sher-I-Kashmir Institute of Medical Sciences

Thank You