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# **urn-randomization**

***Release 1.0***

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## OVERVIEW

### 1.1 Description

Randomization schemes in clinical trials strive to keep assignment of patients to treatment groups free of any deliberate bias so that basis for causal inference can be established. Minimizing bias and maximizing precision of treatment effect estimates are the two principles underpinning the design and execution of these randomization schemes. Urn randomization as described by Wei (1978) is a widely used randomization scheme that helps overcome bias related to unequal distribution of prognostic factors between groups. In comparison with block randomization schemes, this method is less deterministic and is less susceptible to investigator bias due to concealed allotment. It also handles large number of factors better than stratified randomization schemes. This scheme can also be used in trials that are already midway in their recruitment stage to improve factor balance. While other dynamic randomization schemes such as minimization offer more balance, this comes at the cost of being more predictable. Urn randomization schemes also have a tendency to behave like simple randomization as the trial size increases, where imbalances that affect power in estimating treatment effects are less likely. Urn randomization can thus be used for trials with large number of factors that require subgroup analysis, and also to increase precision in interim analyses by ensuring balance.

### 1.2 Authentication

Authentication to the browser interface is handled via OAuth 2.0 using Google. Users will log in via their Google accounts. You will need to provide your Gmail address to the person administering the app so that he or she can register you as an authorized user.

Authentication when using the API is handled via an API key that will be provided to you. It is critical that you store and use this key in a secure manner.

### 1.3 Usage

When you first login, you will be redirected to *Participants* page which displays information related to factor levels of participants already recruited and assigned. This page has bar plots in the top half of the page, visualizing percentages of participants assigned to each treatment group and at different factors/ factor levels (Fig. 1.1).

This page also displays factor information of all participants assigned in a tabular format (Fig. 1.2) in the bottom half of the page. This table has search and sort functionalities and it's contents can also be downloaded as an excel file using the button with *Excel* icon above the table.

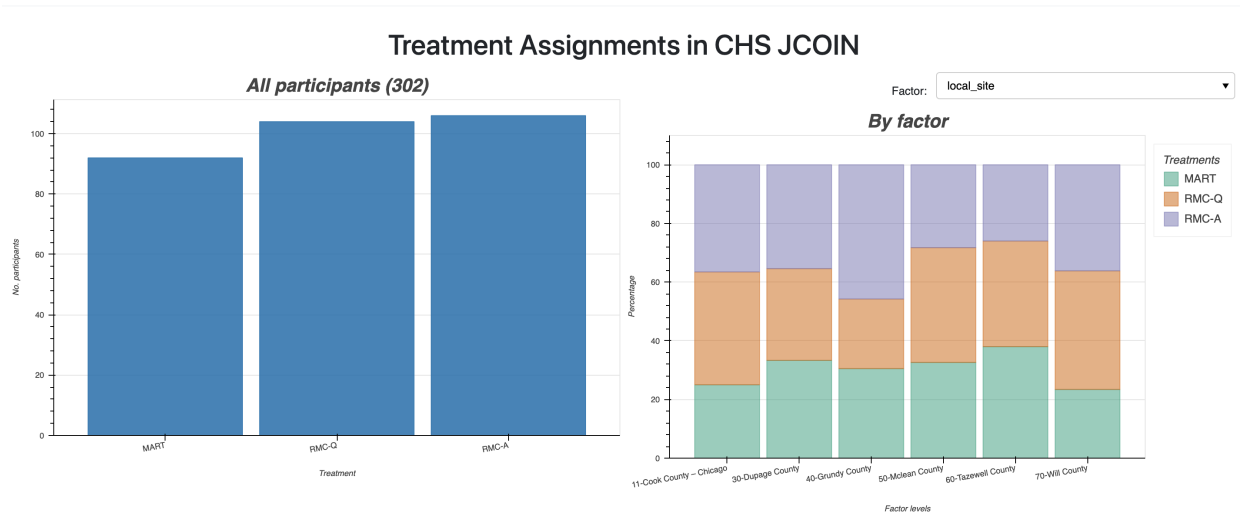


Fig. 1.1: Treatment assignments plots

Randomized participants

Show 5 entries

Search:

id	Local Site	Electronic Monitoring	Incarceration Days	Young Adult	Hispanic Descent	African American	Sex	Prior Opioid Overdose
0	70-Will County	Other	Moderate (13-90)	Yes (18-25)	Other	No	Male	Yes
1	11-Cook County - Chicago	Yes	Low (0-12)	Other (26 or older)	Yes	No	Male	No
10	60-Tazewell County	Other	Moderate (13-90)	Other (26 or older)	Other	No	Male	No
100	40-Grundy County	Other	Moderate (13-90)	Other (26 or older)	Other	No	Male	Yes
101	70-Will County	Other	High (91+)	Other (26 or older)	Other	No	Male	No

Showing 1 to 5 of 304 entries

Previous 1 2 3 4 5 ... 61 Next

Fig. 1.2: Treatment assignments table

### 1.3.1 Randomizing a new participant

To randomize a new participant, click *Randomize Participant* button at the top of the page. This will redirect you to a form (Fig. 1.3) where you can input factor information related to the new participant along with their ID. Click *Submit* after adding all factor details. This will randomize this participant if they do not exist already. Assignment treatment information will be displayed in the next page in the form of a flash message.

Participants / Randomize

**Randomize a new participant**

id

Local Site

11-Cook County – Chicago

Electronic Monitoring

Yes

Incarceration Days

Low (0-12)

Young Adult

Yes (18-25)

Hispanic Descent

Yes

African American

Yes (including mixed)

Sex

Male

Prior Opioid Overdose

Yes

Prior Substance Use Treatment

Any MOUD treatment

Crime Violence Screener Count

Low

Substance Use Days

Low (0-12)

Probation Parole Community Supervision

Yes (1+ days)

Substance Screener Symptoms

Low

Added by

Submit Cancel

Fig. 1.3: Randomize new participant





## 2.1 User management

Users for the Urn Randomization app can only be added via its command line interface.

### 2.1.1 urand\_gui/cli.py create\_db

Initializes flask app DB with available studies & creates user tables

```
urand_gui/cli.py create_db [OPTIONS]
```

### 2.1.2 urand\_gui/cli.py add\_user

Adds a user

```
urand_gui/cli.py add_user [OPTIONS] UNAME EMAIL
```

#### Arguments

**UNAME**

Required argument

**EMAIL**

Required argument

### 2.1.3 urand\_gui/cli.py list\_users

Lists available users

```
urand_gui/cli.py list_users [OPTIONS]
```

## 2.1.4 urand\_gui/cli.py delete\_user

Deletes user linked to email

```
urand_gui/cli.py delete_user [OPTIONS] EMAIL
```

### Arguments

#### **EMAIL**

Required argument

## 2.2 Urn randomization

Urn Randomization app may be accessed via its command line, permitting integration with batch/ scheduler jobs.

### 2.2.1 urand/cli.py

Perform urn randomization as described by Wei (1978)

```
urand/cli.py [OPTIONS] COMMAND [ARGS]...
```

### Options

**-s, --study-name** <study\_name>  
Required Name of study

#### **dummy-study**

Populate a study with dummy data

```
urand/cli.py dummy-study [OPTIONS]
```

### Options

**--n\_participants** <n\_participants>  
Required Study size

**--seed** <seed>  
Required Seed

## export

Export study history to OUTFILE

```
urand/cli.py export [OPTIONS] OUTFILE
```

## Arguments

### OUTFILE

Required argument

## randomize

Randomize new participant

```
urand/cli.py randomize [OPTIONS]
```

## Options

**--id** <id>

Participant ID

**-u, --user** <user>

Username

## upload-participants

Export study history to OUTFILE

```
urand/cli.py upload-participants [OPTIONS] INFILE
```

## Arguments

### INFILE

Required argument



## API ACCESS

Urn Randomization app may be accessed via a web-based API, permitting it to be integrated into existing platforms. Authentication is handled via a user-specific API key provided by the system administrator. It is critical that this key be stored and used in a secure manner.

The API has 3 endpoints, as described below.

**GET /study\_config**

**GET /study\_config**

Return study configuration.

**Example request:**

```
GET /study_config HTTP/1.1
Host: https://rcg.bsd.uchicago.edu/urand
```

**Example response:**

```
HTTP/1.1 200 OK
Vary: Accept
Content-Type: application/json

{
  "message": "Success",
  "results": {
    "D": "range",
    "alpha": 0,
    "beta": 1,
    "factors": {
      "african_american": [
        "Yes (including mixed)",
        "No"
      ],
      "crime_violence_screener_count": [
        "Low",
        "Moderate (1-2)",
        "High (3-5)"
      ],
      "electronic_monitoring": [
        "Yes",
        "Other"
      ],
      "hispanic_descent": [
        "Yes",
```

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```

        "Other"
    ],
    "incarceration_days": [
        "Low (0-12)",
        "Moderate (13-90)",
        "High (91+)"
    ],
    "local_site": [
        "11-Cook County - Chicago",
        "30-Dupage County",
        "40-Grundy County",
        "50-McLean County",
        "60-Tazewell County",
        "70-Will County"
    ],
    "prior_opioid_overdose": [
        "Yes",
        "No"
    ],
    "prior_substance_use_treatment": [
        "Any MOUD treatment",
        "Any other SUD treatment",
        "Other"
    ],
    "probation_parole_community_supervision": [
        "Yes (1+ days)",
        "Other"
    ],
    "sex": [
        "Male",
        "Female"
    ],
    "substance_screener_symptoms": [
        "Low",
        "Moderate (1-2)",
        "High (3-5)"
    ],
    "substance_use_days": [
        "Low (0-12)",
        "Moderate (13-44)",
        "High"
    ],
    "young_adult": [
        "Yes (18-25)",
        "Other (26 or older)"
    ]
},
"starting_seed": 100,
"treatments": [
    "MART",
    "RMC-Q",
    "RMC-A"
],
"urn_selection": "method1",
"w": 1
},
"status": 200

```

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}

**Query Parameters**

- **api\_key** – API Key
- **study** – study name

**Response Headers**

- **Content-Type** – application/json

**Status Codes**

- **200 OK** – participants found for study
- **400 Bad Request** – Invalid request
- **401 Unauthorized** – Unauthorized access
- **404 Not Found** – Study not found

**Return** (status Status code, message Status message/ error info, results Study configuration)**Rtype** (str, str, dict)**GET /study\_participants****GET /study\_participants**

Return list of study participants with their factor levels and treatment assignments

**Example request:**

```
GET /study_participants HTTP/1.1
Host: https://rcg.bsd.uchicago.edu/urand
```

**Example response:**

```
HTTP/1.1 200 OK
Vary: Accept
Content-Type: application/json

{
  "message": "Success",
  "results": [
    {
      "bg_state": {
        "bit_generator": "PCG64",
        "has_uint32": 1,
        "state": {
          "inc": 30008503642980956324491363429807189605,
          "state": 164404244729103591598495580972637239091
        },
        "uinteger": 3586218795
      },
      "datetime": "Wed, 10 Feb 2021 00:01:08 GMT",
      "f_african_american": "Yes (including mixed)",
      "f_crime_violence_screener_count": "Low",
      "f_electronic_monitoring": "Yes",
```

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```

        "f_hispanic_descent": "Other",
        "f_incarceration_days": "Moderate (13-90)",
        "f_local_site": "40-Grundy County",
        "f_prior_opioid_overdose": "Yes",
        "f_prior_substance_use_treatment": "Any other SUD treatment",
        "f_probation_parole_community_supervision": "Other",
        "f_sex": "Male",
        "f_substance_screener_symptoms": "High (3-5)",
        "f_substance_use_days": "High",
        "f_young_adult": "Other (26 or older)",
        "id": "0",
        "trt": "RMC-Q",
        "user": "dummy"
    },
    {
        "bg_state": {
            "bit_generator": "PCG64",
            "has_uint32": 0,
            "state": {
                "inc": 30008503642980956324491363429807189605,
                "state": 175296851311552035585228848780835049764
            },
            "uinteger": 3586218795
        },
        "datetime": "Wed, 10 Feb 2021 00:01:08 GMT",
        "f_african_american": "No",
        "f_crime_violence_screener_count": "Moderate (1-2)",
        "f_electronic_monitoring": "Yes",
        "f_hispanic_descent": "Yes",
        "f_incarceration_days": "Low (0-12)",
        "f_local_site": "70-Will County",
        "f_prior_opioid_overdose": "Yes",
        "f_prior_substance_use_treatment": "Any other SUD treatment",
        "f_probation_parole_community_supervision": "Other",
        "f_sex": "Male",
        "f_substance_screener_symptoms": "Moderate (1-2)",
        "f_substance_use_days": "Moderate (13-44)",
        "f_young_adult": "Yes (18-25)",
        "id": "1",
        "trt": "MART",
        "user": "dummy"
    }
],
    "status": 200
}

```

### Query Parameters

- **api\_key** – API Key
- **study** – study name
- **id** – participant id
- **factor** – Factor value. All study factor levels should be passed

### Response Headers

- **Content-Type** – application/json



**Status Codes**

- 200 OK – participants found for study
- 400 Bad Request – Invalid request
- 401 Unauthorized – Unauthorized access
- 404 Not Found – Study not found

**Return** (status Status code, message Status message/ error info, List of participants)

**Rtype** (str, str, list)

**POST /study\_participants****POST /study\_participants**

Randomize a new participant

**Example request:**

```
POST /study_participants HTTP/1.1
Host: https://rcg.bsd.uchicago.edu/urand
```

**Example response:**

```
HTTP/1.1 200 OK
Vary: Accept
Content-Type: application/json

{
  "message": "Success",
  "results": [
    {
      "bg_state": {
        "bit_generator": "PCG64",
        "has_uint32": 1,
        "state": {
          "inc": 30008503642980956324491363429807189605,
          "state": 164404244729103591598495580972637239091
        },
        "uinteger": 3586218795
      },
      "datetime": "Wed, 10 Feb 2021 00:01:08 GMT",
      "f_african_american": "Yes (including mixed)",
      "f_crime_violence_screener_count": "Low",
      "f_electronic_monitoring": "Yes",
      "f_hispanic_descent": "Other",
      "f_incarceration_days": "Moderate (13-90)",
      "f_local_site": "40-Grundy County",
      "f_prior_opioid_overdose": "Yes",
      "f_prior_substance_use_treatment": "Any other SUD treatment",
      "f_probation_parole_community_supervision": "Other",
      "f_sex": "Male",
      "f_substance_screener_symptoms": "High (3-5)",
      "f_substance_use_days": "High",
      "f_young_adult": "Other (26 or older)",
      "id": "0",
      "trt": "RMC-Q",
    }
  ]
}
```

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```

    "user": "dummy"
  },
  {
    "bg_state": {
      "bit_generator": "PCG64",
      "has_uint32": 0,
      "state": {
        "inc": 30008503642980956324491363429807189605,
        "state": 175296851311552035585228848780835049764
      },
      "uinteger": 3586218795
    },
    "datetime": "Wed, 10 Feb 2021 00:01:08 GMT",
    "f_african_american": "No",
    "f_crime_violence_screener_count": "Moderate (1-2)",
    "f_electronic_monitoring": "Yes",
    "f_hispanic_descent": "Yes",
    "f_incarceration_days": "Low (0-12)",
    "f_local_site": "70-Will County",
    "f_prior_opioid_overdose": "Yes",
    "f_prior_substance_use_treatment": "Any other SUD treatment",
    "f_probation_parole_community_supervision": "Other",
    "f_sex": "Male",
    "f_substance_screener_symptoms": "Moderate (1-2)",
    "f_substance_use_days": "Moderate (13-44)",
    "f_young_adult": "Yes (18-25)",
    "id": "1",
    "trt": "MART",
    "user": "dummy"
  }
],
"status": 200
}

```

### Query Parameters

- **api\_key** – API Key
- **study** – study name
- **id** – participant id
- **factor** – Factor value. All study factor levels should be passed

### Response Headers

- **Content-Type** – application/json

### Status Codes

- **200 OK** – participants found for study
- **400 Bad Request** – Invalid request
- **401 Unauthorized** – Unauthorized access
- **404 Not Found** – Study not found

**Return** (status Status code, message Status message/ error info, results Participant info)

**Rtype** (str, str, dict)

## HTTP ROUTING TABLE

**/study\_config**

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**/study\_participants**

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POST /study\_participants, 13



## Symbols

--id <id>  
     urand/cli.py-randomize command  
         line option, 7

--n\_participants <n\_participants>  
     urand/cli.py-dummy-study command  
         line option, 6

--seed <seed>  
     urand/cli.py-dummy-study command  
         line option, 6

--study-name <study\_name>  
     urand/cli.py command line option, 6

--user <user>  
     urand/cli.py-randomize command  
         line option, 7

-s  
     urand/cli.py command line option, 6

-u  
     urand/cli.py-randomize command  
         line option, 7

## E

EMAIL  
     urand\_gui/cli.py-add\_user command  
         line option, 5

urand\_gui/cli.py-delete\_user  
     command line option, 6

## I

INFILE  
     urand/cli.py-upload-participants  
         command line option, 7

## O

OUTFILE  
     urand/cli.py-export command line  
         option, 7

## U

UNAME  
     urand\_gui/cli.py-add\_user command  
         line option, 5

urand/cli.py command line option  
     --study-name <study\_name>, 6

-s, 6

urand/cli.py-dummy-study command line  
     option  
     --n\_participants <n\_participants>, 6

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urand/cli.py-export command line  
     option  
     OUTFILE, 7

urand/cli.py-randomize command line  
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     --id <id>, 7

--user <user>, 7

-u, 7

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     command line option  
     INFILE, 7

urand\_gui/cli.py-add\_user command line  
     option  
     EMAIL, 5

UNAME, 5

urand\_gui/cli.py-delete\_user command  
     line option  
     EMAIL, 6