urn-randomization

Release 1.0

Research Computing Group, University of Chicago

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CHAPTER

ONE

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.

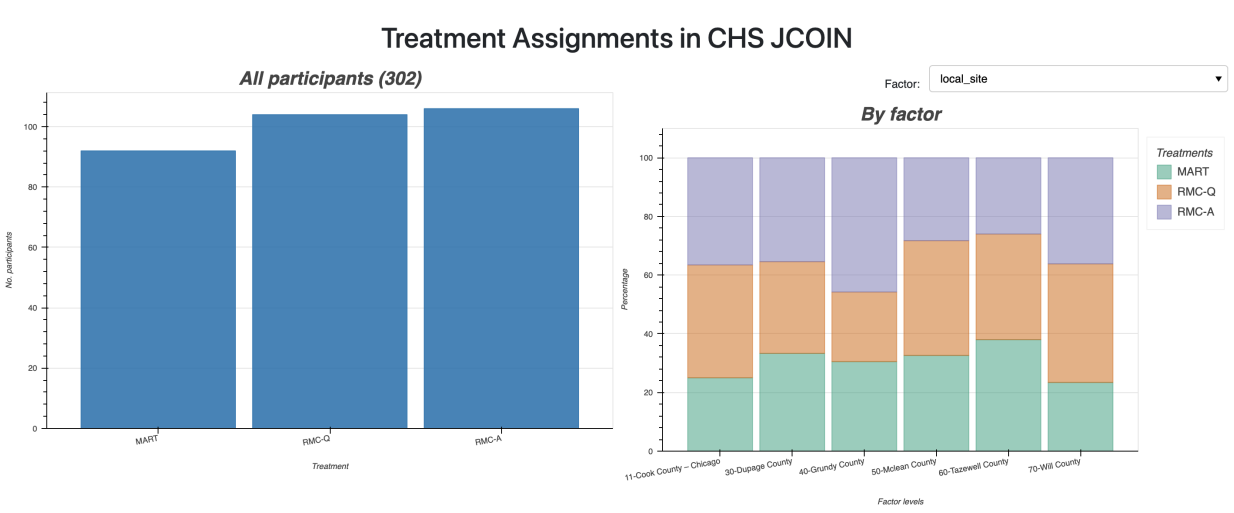

Fig. 1.1: Treatment assignments plots

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.

Fig. 1.3: Randomize new participant

CHAPTER

TWO

CLI

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

2.1 urand.cli

Perform urn randomization as described by Wei (1978)

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

Options

-s, --study-name <study_name>
Required Name of study

2.1.1 dummy-study

Populate a study with dummy data

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

Options

--n_participants <n_participants>
Required Study size

--seed <seed>
Required Seed

2.1.2 export

Export study history to OUTFILE

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

Arguments

OUTFILE
Required argument

2.1.3 randomize

Randomize new participant

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

Options

--id <id>
Participant ID

-u, --user <user>
Username

CHAPTER

THREE

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 – participnts 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":300085036429809563244913634298071896O5,
                    "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":300085036429809563244913634298071896O5,
                    "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 – participnts 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":300085036429809563244913634298071896O5,
               "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":300085036429809563244913634298071896O5,
                    "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 – particiipnts found for study
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- 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

/study_participants

INDEX

Symbols

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